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Clinical Studies - Outcomes

Cod: T049

PROTECTIVE EFFECT OF ORAL ADMINISTRATION OF FOLIC ACID AGAINST DIMETHYLNITROSAMINE – INDUCED ACUTE LIVER DAMAGES IN RATS

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Background:
Hepatoprotective effects of folic acid on chemical-induced liver fibrosis in rats have been previously reported. The aim of the present study was to investigate whether folic acid administration ameliorates dimethylnitrosamine (DMN) – induced acute liver damages in rats.

Methods:
The 48 adult male Sprague Dawly rats were divided into six groups of 8 rats each. One 3 rat's group were injected with DMN intraperitoneally. Following a single dose of 40 mg/kg DMN, either saline (hepatitis control) or folate (0.8 mg/kg and 2.4 mg/kg) was administered for 21 days once daily. In another 3 rat's group water (healthy control)or folate were gavaged for 21 days, following a single injection of saline. On the 22nd day, all rats in each group were killed and their blood and liver samples were obtained for further analyses. The plasma levels of liver enzymes,total protein, albumin and bilirubin were measured. Also, levels of reduced glutathione (GSH), malondialdhyde (MDA) and activity of catalase (CAT), glutathione reductase (GR) and glutathione peroxidase (GPx) were measured in liver homogenate. Hepatic fibrotic changes were evaluated by histopathogical examination.

Results:
DMN caused hepatic fibrotic changes, decreased albumin level and increased the plasma enzyme levels, whereas folic acid prevented these changes. DMN administration resulted in increased MDA levels, and decreased GSH and CAT and GR levels, whereas folate reversed these effects. The results indicate that high dose of folic acid exhibits a better hepatoprotective effect.

Conclusions:
The present study suggests that folic acid acts as an antioxidant and may be a therapeutic choice to reduce oxidative stress against DMN-induced liver fibrosis in rats.

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Clinical Studies - Outcomes

Cod: T050

EVALUATION OF THE STRATUS CS/STRATUS CS 200 ACUTE CARE DIAGNOSTIC SYSTEMS AND ADVIA CENTAUR XP IMMUNOASSAY SYSTEM FOR CARDIAC TROPONIN I

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Background: Troponin I (cTnI) is recognized as the preferred biomarker in detection of myocardial infarction (MI) given its high clinical sensitivity and myocardial tissue specificity. The objective of this study was to demonstrate diagnostic equivalence between the cTnI method on the point-of-care Stratus® CS/Stratus CS 200 Acute Care™ Diagnostic Systems and the laboratory-based ADVIA Centaur® TnI-Ultra® assay on the ADVIA Centaur XP system, both from Siemens Healthcare, in the determination of MI. The Stratus CS platforms and ADVIA Centaur XP Immunoassay systems each display optimal precision at their respective 99th percentile upper reference limit (URL), with a CV ≤10%, allowing reliable detection of changing cTnI values.
Methods: A comparison study was performed at the Siemens Healthineers Edgewater site in Norwood, MA, using frozen plasma samples from patients suspected of having MI. Samples were collected under IRB protocol through an external vendor. Two time points were obtained per patient, including at time of presentation and the next sequential blood draw. Samples were frozen and shipped for concurrent processing on the Stratus CS platforms and ADVIA Centaur XP Immunoassay system. Patients were categorized as positive or negative for MI based on the presence or absence of at least one elevated cTnI value for each platform relative to the URL. Final diagnosis according to the Third Universal Definition of MI was provided for each patient as the reference standard for comparison.
Results: Contingency tables were generated comparing the patient outcome as determined by the Stratus CS platforms and ADVIA Centaur XP Immunoassay system to the reference standard. The 99th percentile URL for MI on the Stratus CS platforms is 0.07 ng/mL, and for the ADVIA Centaur XP Immunoassay system is 0.04 ng/mL. The common measuring interval is 0.03–50.0 ng/mL. Comparative receiver operating characteristic (ROC) curves were generated for each time point to visually display the sensitivity and specificity of each platform across the measuring interval. Concordance measures included sensitivity, specificity, area under the curve, paired differences, confidence intervals (CI), and p values for each system. Example: Stratus CS 200: Sensitivity, CI (96.0%, 86.5-98.9%); Specificity, CI (100.0%, 94.0–100.0%).
Conclusion: Clinical concordance was demonstrated between the Stratus CS platforms and ADVIA Centaur XP Immunoassay system for Troponin I.

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Clinical Studies - Outcomes

Cod: T051

ANEURYSMAL SUBARACHNOID HEMORRHAGE: ROLE OF S100B AND NEURON-SPECIFIC ENOLASE AS OUTCOME PREDICTORS

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Background: Roughly 80% of non-traumatic blood extravasation into the subarachnoid space results from aneurysmal subarachnoid hemorrhage (aSAH), a condition with an estimated incidence rate of 4–28 per 100,000 inhabitants. Several biomarkers have been proposed for cerebral event identification in clinical practice. The aim of this study is to evaluate the prognostic value of S100B and Neuron-specific enolase (NSE) serum levels in patients with aSAH.

Methods: 63 patients with aSAH diagnosis admitted to the Neurosurgical Intensive Care Unit (ICU) of the Virgen del Rocío University Hospital were included in the study. Venous blood samples were collected daily from day 0 (initial bleeding) until day 4 to determine S100B and NSE. Outcome was assessed at 12-month follow up according to Glasgow Outcome Scale (GOS), and dichotomized according to favorable (GOS 4-5) and unfavorable (GOS 1-3) outcome.

Results: During the follow-up period, median values for serum S100B decreased from day 0 to day 2, showing statistical significant differences between samples 0-1 ($p=0.026$) and 1-2 ($p=0.032$): day 0= 0.152 µg/L (IQR 0.084-0.211), day 1= 0.119 µg/L (IQR 0.067-0.224), day 2= 0.090 µg/L (IQR 0.061-0.183), day 3= 0.090 µg/L (IQR 0.056-0.170), day 4= 0.097 µg/L (IQR 0.057-0.177). NSE results just significantly decreased from day 0 to 1 ($p<0.001$): day 0= 16.87 µg/L (IQR 11.21-25.42), day 1= 11.6 µg/L (IQR 7.38-16.11), day 2= 11.21 µg/L (IRQ 7.84-15.31), day 3= 11.41 µg/L (IQR 7.71-22.36), day 4= 13.45 µg/L (IQR 8.32-20.20).

At 12 months of the bleeding, 24 patients presented favorable outcome and 39 patients unfavorable outcome. S100B levels from the 5 days samples were higher in patients with 12-month unfavorable outcome ($p<0.05$). In reference to NSE, just the fifth sample (day 4) was statistically higher in favorable outcome patients ($p=0.033$).

ROC analysis showed that all S100B samples (AUC: day 0= 73.3%, day 1= 73.4%, day 2=80.6%, day 3=74.0%, day 4= 76.9%) and day 4 NSE sample (AUC 69.1%) accurately discriminate between favorable and unfavorable outcome.

Conclusions: Both biomarkers are useful tools for predicting 12-month outcome in aSAH patients. Nevertheless, S100B protein showed higher prognostic capacity than NSE.

This study was funded by a grant from Consejería de Igualdad, Salud y Políticas Sociales de Andalucía, Spain (PI-0136-2012).

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Clinical Studies - Outcomes

Cod: T052

ASSESSMENT OF THE EFFECTIVENESS OF ACE INHIBITOR TREATMENT: PERSONALIZED THERAPY FOR IMPROVING OUTCOMES

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ACE inhibitors (ACEi) are first line drugs of hypertension and heart failure therapy. Both prescription of drugs and monitoring the efficacy of ACEi treatment aim to achieve optimal therapeutic outcomes.
At the Institute of Cardiology, University of Debrecen we set up a method suitable for the evaluation of ACEi treatment efficacy. Serum ACE activity was determined in blood samples of 501 hypertonic patients. In addition, their clinical history and medication was also recorded.
Blood pressure of the patients was within the target value independently from the application of ACEi (without ACEi was 131.9±1.6 / 80.5±0.9 mmHg, n=118; with ACEi 134.3±1.0 / 80.5±0.6 mmHg, n=383). We directly measured the level of ACE-inhibition in patients' sera. Patients with ACEi therapy had higher level of ACE inhibition (93±8% inhibition, n=383, $p<0.001$) than in patients without ACEi treatment (72±7% endogenous inhibition, n=118). 66 patients treated with ACEi (17.2%) presented ineffective inhibition and they had a higher blood pressure value (139.3 ± 3.0 / 85.6 ± 2.0 mmHg, n=66) than that of patients treated effectively (133.3 ± 1.0 / 79.4 ± 0.6 mmHg, n= 317). Insufficient patient compliance was supposed, thus we also examined statin treatment efficacy in the same patients. Those patients, who take also statins but take ACEi improperly presented higher total cholesterol levels than those, who take ACEi poperly (5.90 ± 0.3 mM, n= 25, 5.11 ± 0.1 mM, n=111, $p<0.005$). Patients with insufficient ACE inhibition were contacted and asked to pay a special attention to their medications and to come back for an additional visit. Only 55% of the patients came back. 17% of the patients had effective ACE inhibition at their second visit. The dose was increased in 9% of the cases resulting in sufficient level of ACE inhibition. 17% of the patients reported that ACE inhibitor was not taken because of side effects (which fact was not previously mentioned to the cardiologist). Effectiveness of the adjustment of the therapy was verified by changes in blood pressure (decrease in mean arteriolar blood pressure from 122±4 to 109±4 mmHg, $p=0.003$).
1/5 of patients enrolled in this study receive insufficient ACE inhibition, which can probably be explained by their improper compliance. With our method, physicians can gather information about the efficacy of ACEi treatment from a single blood test, so they can modify drug treatment or influence the patients' compliance.

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Clinical Studies - Outcomes

Cod: T053

REFERENCE RANGES OF SOLUBLE CD14 SUBTYPE (PRESEPSIN) AFTER UNCOMPLICATED MAJOR SURGERY: COMPARISON WITH PROCALCITONIN, CRP, AND LEUKOCYTES

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Background: Presepsin is an emerging sepsis biomarker. The aim of the pilot study was to demonstrate the interpretative limits of presepsin, procalcitonin, C-reactive protein (CRP), and leukocytes measured repeatedly in patients without infectious complications after major surgery.
Methods: The postoperative SIRS model included 24 consecutive patients after major cardiac or abdominal surgery without any signs of sepsis or infectious complications up to 30 days after surgery. Plasma presepsin, procalcitonin, CRP, and leukocytes were measured serially for up to 7 days following surgery.
Results: Early peaks were found in presepsin and leukocyte concentrations (median concentrations of 819 ng/L and 11.4 x 10^9/L with 95th percentiles of 2017 and 17.8, respectively, both within the first 24 hours postoperatively). Procalcitonin peaked on the 1st day after surgery (median 0.54 μg/L, 95th percentile 4.76), while CRP peaked on the 3rd day after surgery (median of 133.3 mg/L, 95th percentile of 287.5). The peak values were 1.5, 9, 66, and 1.9 times higher than the basal values for presepsin, procalcitonin, CRP, and leukocytes, respectively.
Conclusions: Presepsin is less influenced by postoperative SIRS than procalcitonin or CRP and may therefore act as a valuable biomarker for the detection of infectious complications in patients after major surgery.

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Clinical Studies - Outcomes

Cod: T054

REDUCING THE TURNAROUND TIME OF THE PRE-ANALYTICAL PHASE BY APPLICATION OF A RAPID CENTRIFUGATION PROFILE

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Background
Specimen centrifugation in clinical laboratories is one of the most time-consuming pre-analytical activities, which can take up to 15 minutes. In order to enable a higher sample throughput, we compared a centrifugation profile of 4,000g for 4 min with clinical standard profiles and investigated whether this rapid centrifugation profile is clinically acceptable for a broad panel of clinical tests. Platelet count was determined as an indicator of sample separation quality.

Methods
Blood collected from 153 healthy donors into 2 lithium heparin tubes with gel separator (BD Vacutainer® PST™ II) and 2 sodium citrate tubes (BD Vacutainer®) was centrifuged using a Beckman Coulter Centrifuge (rotor radius: 175.5 mm) at 4,000g for 4 min or with the control profile (1,200g for 10 min for lithium heparin tubes or 1,500g for 15 min for sodium citrate tubes) and was tested for 30 routine and hemolysis-sensitive clinical chemistry tests, 9 routine and fibrin-sensitive immunoassays, 4 coagulation tests and platelet count.
Blood collected from 40 healthy donors into 2 sodium citrate tubes was also centrifuged at 4,000g for 4 min or with the control profile (at 1,500g for 15 min) and then tested for platelet count and two special coagulation tests (Factor VIII and IX) using fresh and frozen-thawed samples.

Results
Weighted Deming Fit regression analysis demonstrated comparable results across the range of sample concentrations tested for each included analyte. No clinically significant difference for hemolysis-sensitive tests (Aspartate Aminotransferase, Potassium, Lactate Dehydrogenase) was detected nor did we find increased hemoglobin concentration. The achieved sample separation quality was high as indicated by platelet count, being on average below 10,000 platelets/µl. Clinical acceptable results were obtained for Factor VIII and IX using fresh and frozen-thawed samples.

Conclusion
The data demonstrates equivalence for tests of all three disciplines between the centrifugation profile 4,000g for 4 min and the control profiles. This centrifugation profile thereby provides a solution which considerably shortens the time required for obtaining test results and which concurrently preserves high sample quality.

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Clinical Studies - Outcomes

Cod: T055

PERCENTAGE DISTRIBUTION OF MALE INFERTILITY IN MARRIED COUPLES IN OHRID-STRUGA-DEBAR REGION IN R. MACEDONIA

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BACKGROUND
Spermogram and sperm testing are the main analyses for male population in order to confirm or deny infertility. According to official WHO data, the frequency of infertility in married couples is about 10-15% of the total number of married couples. Attention is drawn to the upward trend in the proportion of male factors in sterile marriages. According to the latest study, the male "contribution" to infertile marriages is starting to dominate over the female`s. Over the past 20 years, male infertility as cause, has increased from 30% to 50% and continues to grow steadily. Over the past half century, sperm count has decreased by almost 3 times. Such a trend indicates the progressive deterioration of ejaculate quality. The aim of our study was to calculate male infertility among married couples in Ohrid-Struga-Debar region.

METHODS
We use methods according to WHO laboratory manual for the Examination and processing of human semen (fifth edition). After semen collection is done by properly standardized procedure, the following steps were involved in semen analysis: volume of ejaculate, viscosity, liquefaction, pH, appearance, total number per ejaculate, concentration per mL, total motile, non progressive, immotile (native preparation), live and dead spermatozoa (eosin-nigrosin smears), normal forms, abnormal heads, abnormal midpieces, abnormal tails, excess residual cytoplasm (Papanicolaou staining procedure) and non sperm cells.
Obtained results were analyzed with IBM SPSS Statistics.

RESULTS
In a period of 9 years (oct. 2007 – oct. 2016) we examined 523 sperm samples from infertile marriages. Male age range was from 25 to 45 years old. 14 of them were excluded due to insufficient data. The diagnosis was made by reference intervals according to WHO laboratory manual. They were classified in 8 groups. From 509 samples, 66,4% were classified in normozoospermia; 12,8% oligozoospermia; 3,9% asthenozoospermia; 0,6% teratozoospermia; 7,8% oligoasthenozoospermia; 1,0% oligoteratozoospermia; 1,8% oligoasthenoteratozoospermia and 5,7% azoospermia.

CONCLUSIONS
Since 33,6% accounts to abnormal diagnostic groups, we can concluded that 1/3 of infertility in married couples is due to male infertility which correspondents with official WHO data.

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Clinical Studies - Outcomes

Cod: T056

BIOCHEMICAL SAMPLE TESTING IN NEW MINICOLLECT® BLOOD COLLECTION TUBES

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Background: Where small sample volumes are critical, especially for infants, elderly or obese patients, the new MiniCollect tube allows highest flexibility and accuracy by collecting blood in unprecedented simplicity. The MiniCollect Serum Separator and Lithium Heparin Separator tubes are intended to collect, transport, separate and process capillary blood for testing serum and plasma, respectively in the clinical laboratory.
Methods: A study was done at Steyr Hospital (Austria) using MiniCollect tubes with old design vs. new design. Altogether, 80 hospitalized and 50 healthy subjects were recruited. Informed consent was given by all donors and the study was approved by EC Upper Austria. Directly after blood collection, the tubes were inverted 8 times and processed according to the IFU for MiniCollect tubes. After centrifugation for 10 min at 3000g, 28 common biochemical analytes were tested using an AU680 and DxI800 (Beckman Coulter). Analysis was done with the instrument's accompanying reagents.
Results: Evaluation of all clinical data and deviations was done on the basis of the maximum allowed deviation for a single value according to the guidelines of the German Association of Quality Assurance of Laboratory Testing (Rilibäk). The utilization of tubes with old and new design for performance testing did not reveal any clinically nor statistically significant deviations ($p<0.05$). The values in both serum tubes resulted in an initial highest deviation of 3.2%, and in plasma tubes of 4.4%. Comparable highest deviations for initial values in relation to 48h values were obtained for serum (5.3%) and plasma (6.4%).
Conclusion: From a clinical perspective, the MiniCollect Serum Separator and Plasma Separator tubes with the new design are substantially equivalent to the tubes with the old design. The newly designed tubes provide an essentially enhanced blood collection device for skin-puncture testing. As the fundamental advantage is the guarantee of the sample integrity for high quality results in case of critical sample collections and transport of the tubes, the supporting information and data obtained from adult populations are more than adequate to establish safety and effectiveness for the patient indication.

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Clinical Studies - Outcomes

Cod: T057

INVESTIGATING EFFECT OXIDANT-ANTIOXIDANT SYSTEMS SOURCES IN MALE INFERTILITY VARICOCELE AND IDIOPATHIC IN SEMEN PLASMA

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BACKGROUND
The aim of this study were to investigate seminal oxidant-antioxidant activity in infertil men. In addition, as varicocele is to provide new approaches to both the pathogenesis of idiopathic infertility.
METHODS
This study was conducted the new laboratory factors related to the pathogenesis of infertility and to uncover new scientific data for the diagnosis and treatment of idiopathic and varicocele-induced infertility. Made by us in literature was determined to be the first. This research project was supported by TUBITAK (THE SCIENTIFIC AND TECHNOLOGICAL RESEARCH COUNCIL OF TURKEY). Liquefied which the semen sample was centrifuged at 3000 g for 15 minutes. The resulting liquid was transferred to a sterile 1 cc aliquot of seminal Falcon tube and stored at -80 °C for biochemical analysis. On the day of the analysis, the TTL and PON1 levels were examined using a fully automatic analyser (Architect C16000; seri no: C1600549, Abbott). The test parameters investigated in this study; Total Anti-oxidant capacity (TAC), Total oxidant status (TOS), Total thiol (TTL), Paraoxonase (PON1) and Arylestereaz (ARE) levels. The results were expressed; TAC as mmol Trolox equivalent/L, TOS as μmol H2O2 equivalent/L, ARE activity was defined as U/L and PON 1 activity was expressed as U/L. The ratio of TOS to TAC was accepted as the oxidative stress index (OSI). Rel Assay Diagnostics kit was used in the study. Statistical values were analyzed with SPSS 23 software package.
RESULTS
The comparison between the three groups (Kruskal-Wallis test), the average of the parameters between, there was no significant statistical difference. Those infertile and fertile were compared using the Mann-Whitney U test. Infertile patients higher PON1 values more than the other fertile was determined (significant statistical, $p = 0.042$). The other test parameters between the two groups (TAC, TOS, TTL, OSI), was not statistically significant ($p = 0.391$, 0.488, 0.084, 0.620). The p value could not be determined for ARE because unread.
CONCLUSIONS
Infertility patients semen detected in plasma PON1 value of height, brings to mind that there is a negative relationship. On the other hand no doubt these issues need to be clarified by further research.

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Clinical Studies - Outcomes

Cod: T058

AN IMMUNOHISTOCHEMICAL, HISTOPATHOLOGICAL AND BIOCHEMICAL ANALYSIS OF THE NEUROPROTECTIVE EFFECTS OF MEMANTINE, AND CURCUMIN AFTER CEREBRAL ISCHEMIA-REPERFUSION INJURY IN ELDERLY RATS

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Backroud: Cerebral ischemic stroke is one of the leading causes of human death and disability in the world. The aim of our study was to investigate the protective effects of curcumin(CUR) and memantine(MEM) on cerebral ischemia/reperfusion (I/R) in elderly rats.

Materials and Methods: The experiments were designed in 40 Wistar Hannover rats, randomly allotted into one of five groups(n=8): CUR(Group I), MEM(Group II), CUR+MEM(Group III), ischemia(Group IV), and sham-operated(Group V). The model adopted was that of surgically-induced cerebral ischemia, performed by means of bilateral common carotid artery occlusion for 30 minute, followed by reperfusion for another 72 hour. Biochemical parameters such as tumor necrosis factor-α(TNF-α), interleukin-6(IL-6), lactate dehydrogenase(LDH), catalase(CAT), glutathione peroxidase(GSPx), xanthine dehydrogenase(XDH), superoxide dismutase(SOD), and malondialdehyde(MDA) were investigated in brain tissue and serum of the rats in all groups. Brain tissues were evaluated immunohistochemically and Caspase-3 antibody. Apoptotic Index(AI) was used as a measure of the extent of apoptosis to detect neuronal loss in the brain tissue samples.

Results: Tissue and serum IL-6, TNF-α, MDA, LDH levels were found statistically significantly lower in the treated group compared to the untreated group ($p < 0.001$). Tissue and serum GSPx, SOD and CAT levels were found statistically significantly higher in the treated group compared to the untreated group ($p < 0.001$). Histopathologically, no statistically difference was detected between the untreated and treated groups. Statistical difference was not detected when comparing control and treated groups with positive apoptotic index ($p > 0.05$).

Conclusion: In conclusion, in this study, although CUR, MEM and CUR+MEM is effective in preventing oxidative damage following cerebral ischemia, they were found to be ineffective in preventing tissue damage.

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Clinical Studies - Outcomes

Cod: T059

PROGRESSIVE INCREASE OF PLASMA LEVELS OF GROWTH DIFFERENTIATION FACTOR-15 (GDF-15) IN YOUNG PATIENTS WITH TYPE 1 DIABETES MELLITUS (T1D) IS ASSOCIATED WITH RENAL FUNCTION DECLINE

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Background: Diabetic nephropathy constitutes a major long-term complication in patients with T1D and its diagnosis is based on microalbuminuria. GDF-15 is a protein belonging to the TGF-beta superfamily that has a role in regulating inflammatory and apoptotic pathways in injured tissues and during disease processes. Recent studies showed the involvement of GDF-15 in cardio-renal events therefore we aimed to investigate in an observational follow-up study its role in unravelling early diabetic nephropathy and its impact as potential risk marker for cardiovascular morbidity.
Methods: 56 patients with T1D, aged 13.1±3.2y and 49 healthy controls aged 12.8±6.6y were recruited. Along with standard blood and urine chemistry, measurements of Neutrophil Gelatinase-Associated Lipocalin (NGAL), Cystatin-C and GDF-15 were performed. eGFR values were calculated from Cystatin C based e-GFR equations. The measurements were performed at enrolment and after 12-15 months.
Results: At baseline, mean GDF-15 levels were not significantly different between children with T1D (289.5pg/mL) and controls (278.6pg/ml). At re-evaluation, mean GDF-15 in patients increased (366.7pg/mL), ($p<0.001$). The increment of GDF-15 levels occurs in 40/56 (71.4%). The increase of GDF-15 levels was accompanied by a weak significant negative correlation with eGFR values ($p=0.03$). Similar, but not in this degree was the increment of serum NGAL levels ($p=0.02$), while urine NGAL levels increment didn't reached significant difference ($p>0.09$). Furthermore, GDF-15 levels correlated and positively with both total Cholesterol ($p=0.033$) and LDL-C ($p=0.009$).
Conclusions: To our knowledge, this is the first study to demonstrate that the progressive increase of plasma levels of GDF-15 in patients with T1D is associated with renal function decline, thus suggesting that GDF-15 might serve as a marker of an early renal structural injury of glomerular or tubular origin. Since, nowadays, an automated method for the measurement of GDF-15 levels is available it must undergo rigorous validation in multiple cohorts prior to its implementation in the clinical assessment, as effective management and treatment approaches are needed to minimize the rates of severe cardio-renal morbidity and mortality in young patients with T1D.

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Clinical Studies - Outcomes

Cod: T060

THE PREPRANDIAL GLUCAGON-LIKE-PEPTIDE-1 (GLP-1) AND AMYLIN LEVELS ARE LOW IN PATIENTS WITH CELIAC DISEASE: EFFECT OF TREATMENT AND COEXISTENCE OF TYPE-1 DIABETES (T1D)

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Background: Celiac disease (CD) is a unique autoimmune disorder that is induced, in genetically predisposed persons, by the ingestion of gluten, the major storage protein of wheat and similar grains. GLP-1 and Amylin are two peptide hormones implicated in gut-brain-axis signals and functions. GLP-1 may enhance peripheral glucose disposal and insulin sensitivity, while amylin is co-secreted with insulin from pancreatic islet beta-cells in response to nutrient ingestion, incretin hormones and neural input. We aimed to evaluate GLP-1 and Amylin levels in patients with CD and possible association of these hormones with clinical features of the disease.
Methods: Forty-seven CD children: 12 untreated (UCD), 22 treated with gluten-free-diet (TCD) and 13 treated CD with co-existing T1D (DCD) and 18 healthy controls (HC) were enrolled. Preprandial GLP-1 and amylin levels were measured using the Luminex xMAP® Technology with the Milliplex Map assay kit.
Results: Serum GLP-1 levels were significantly reduced in all patients compared to HC (UCD 57.0±5.8pg/mL, TCD 59.9±7.2pg/mL, DCD 42.8±8.6pg/mL, HC 85.7±12.4pg/mL) ($p<0.01$). Serum amylin levels were significantly reduced in all patients, especially in the group of DCD patients, than in HC (UCD 142.6±33.9pg/mL, TCD 189.5±27.9pg/mL, DCD 89.1±25.7pg/mL) ($p<0.01$). GLP-1 and amylin levels correlated positively with insulin ($r=0.410$, $p=0.004$ and $r=0.370$, $p<0.01$, respectively), while only amylin correlated positively with serum triglycerides ($r=0.698$, $p<0.001$). No correlations were found between these gut hormones and sex, age, BMI, age at diagnosis, duration of disease, anti-Tg antibodies, HbA1c, Glu, t-Chol, HDL-C, Apo AI and Apo B.
Conclusions: These findings indicate an important role of GLP-1 and amylin in the pathophysiology of CD. Nowadays, new efforts are focused in elucidating the implication of neuropeptides in the microbiota-gut-brain-axis and to address the information carriers from the gut to the brain and vice-versa. Clarification of their role as markers of remission and/or glycemic control in T1D patients could possibly offer significant tools to the clinical management of patients with these autoimmune disorders or even allow the development of new therapeutic strategies for food intake and glycemic homeostasis.

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Clinical Studies - Outcomes

Cod: T061

WITHIN-TUBE STABILITY OF SELECTED ROUTINE CHEMISTRY ANALYTES AND IMMUNOASSAYS IN BD VACUTAINER® BARRICOR™ PLASMA BLOOD COLLECTION TUBES IN COMPARISON WITH BD VACUTAINER® PST™ II AND SST™ II ADVANCE TUBES AT MULTIPLE TIME POINTS POST-CENTRIFUGATION

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Background. Cellular contamination (red blood cells, white blood cells, platelets) in plasma is known to affect the stability of analytes that are impacted by cell-mediated metabolism and cell lysis. The mechanical separator technology in the BD Vacutainer® Barricor™ Tube helps to reduce cellular contamination in plasma samples. Multiple studies were performed to evaluate within-tube stability of selected chemistry analytes and immunoassays in BD Barricor™ Tubes compared with BD Vacutainer® PST™ II (BD PST™ II), and BD Vacutainer® SST™ II Advance (BD SST™ II) Tubes at multiple time points post-centrifugation.

Methods. Ninety-two subjects participated in the study, which evaluated within-tube stability for selected chemistry analytes and immunoassays. Clinical equivalence or acceptable performance was assessed for BD Barricor™, BD PST™ II and BD SST™ II Tubes at 24h, 3 days, or 7 days versus 0h. For analytes that were not stable at 24h in BD Barricor™ or BD PST™ II Tubes, a study was conducted with 40 subjects to determine stability at 6h, 12h, and 18h from centrifugation with room temperature storage. BD SST™ II was not evaluated for analyte stability at < 24 hours.

Results. For all analytes, within-tube stability for 7 days was observed in BD Barricor™ Tubes with the following exceptions: folate was stable for 24h and CO2 and glucose were stable for 18h. For BD PST™ II, within-tube stability for 7 days was observed for all analytes except LDH and K, which were stable for 24h, Phos, which was stable for 3 days, and CO2 and glucose, which were stable for 18h. For BD SST™ II, within-tube stability for 7 days was observed for all analytes except CO2, complement C3 and K, which were stable for 3 days; triglycerides and folate were not stable at any time point ≥ 24h.

Conclusions. Within-tube stability of 7 days was observed in BD Barricor™ Tubes for all analytes and immunoassays except folate, which was stable for 24h and CO2 and glucose, which were stable for 18h. BD Barricor™ demonstrated better stability than BD PST™ II for analytes impacted by cellular contamination (LDH, K, Phos).

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Clinical Studies - Outcomes

Cod: T062

EVALUATION OF THE BD VACUTAINER® BARRICOR™ PLASMA BLOOD COLLECTION TUBE FOR SELECTED DIAGNOSTIC INFECTIOUS DISEASE ASSAYS

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Background. Serum has been the preferred sample type for infectious disease testing. However, the use of plasma has the potential to reduce turnaround time. A plasma blood collection tube with mechanical separator technology (BD Vacutainer® Barricor™ Plasma Blood Collection Tube) was evaluated in comparison with BD Vacutainer® PST™ II, BD Vacutainer® SST™ II and BD Vacutainer® Serum Tubes for selected diagnostic infectious disease assays (Core – Anti-HBc, AUSAB – Anti-HBs, HBsAg, Anti-HCV, Multispot HIV-1/HIV-2 Rapid Test, HIV Ag/Ab Combo, Anti-HIV 1/2, Syphilis Screen [anti-T. pallidum assay], Syphilis [Non-Treponemal Assay]).

Methods. Subjects known to test positive and negative for each infectious disease assay (except for anti-HIV-2, anti-HIV Group O and HIVp24 antigen) were enrolled from the outpatient and/or inpatient populations at multiple sites. A total of 914 subjects completed the study. Fifty-five contrived specimens were tested for anti-HIV-2, anti-HIV-1 Group O, HIV p24 antigen and HBsAg.

Blood was collected into the study tubes in random order and the tubes were centrifuged at 3,000g for 10 minutes within 2 hours of collection. Samples collected at the primary site were stored at room temperature and tested within 6 hours of centrifugation. Samples collected at secondary sites were aliquoted, frozen and shipped to the primary site for testing. Testing was performed for the designated assays using the Abbott ARCHITECT® ci4100, Ortho Diagnostics Vitros® ECi or Siemens Immulite® 2000. Syphilis (Non-Treponemal Assay) was performed using an ASI RPR card test; Multispot HIV-1/HIV-2 Rapid Test was performed with a Bio-Rad Multispot Test.

Results. For each assay, the overall agreement rate obtained between the BD Barricor™ Tube and each comparator tube (BD PST™ II, BD SST™ II and BD Serum) was at least 95% with 95% confidence. Therefore, the performance of the BD Barricor™ Tube was acceptable for the selected infectious disease assays.

Conclusion. The BD Barricor™ Tube demonstrated clinically acceptable performance when compared to BD PST™ II, BD SST™ II and BD Serum Tubes for the selected infectious disease assays, thus providing a viable option for blood collection for infectious disease testing.

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Clinical Studies - Outcomes

Cod: T063

MODELS 1B AND 2 ACCORDING TO EFLM CONSENSUS CONFERENCE GIVE THE SAME SPECIFICATION FOR ALLOWABLE TOTAL ERROR (TEA) OF PLASMA GLUCOSE MEASUREMENT

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BACKGROUND: The 2014 EFLM Consensus Conference (CC) identified outcome- and biological variation (BV)-based as the highest hierarchical models for defining analytical performance specifications (APS) of a measurand. Fasting plasma glucose (PG) plays a central role in diagnosis of diabetes mellitus (DM) and decision limits for the definition of glycaemic-related conditions have been established. As direct studies investigating the impact of performance of PG measurement on clinical outcome are not available, we aimed to apply an indirect outcome model (1b according to CC) to derive APS for TEa, by investigating the impact of performance of PG measurement on clinical classifications of fasting subjects. The 1b-TEa was validated by comparison with TEa obtained using PG BV data (CC model 2). Since PG is under strict homeostatic control, robust BV data can be derived. In particular, we employed data from the study by Carlsen et al. (CCLM 2011;49:1501) (CVI, 5.4% and CVG, 5.6%), which totally fulfilled the EFLM checklist for BV study appraisal.
METHODS: The decision limits defining impaired fasting PG (IFG) concentrations (110 to 125 mg/dL) were considered and 1b-TEa was derived by assuming that a subject with a fasting PG of 117.5 mg/dL should be differentiate from healthy condition from one side (<110 mg/dL) and a frank DM from the other side (>125 mg/dL). Model 2-TEa was estimated according to the equation: TEa = [1.65 x 0.5CVI + 0.25(CVI2 + CVG2)0.5].
RESULTS: A subject with fasting PG of 117.5 mg/dL will not be misclassified as diabetic or healthy if TE of PG measurement is <7.5/117.5 = <6.38%. The corresponding TEa derived from PG biological variability was ±6.4%.
CONCLUSIONS: The described model 1b, based on assumptions drawn from what evidence there is about the definition of glycaemic-related conditions and thereby on the probability of subject outcome, is applicable for the definition of TEa of PG measurement. The similarity with TEa derived from model 2 confirms the equivalence of the two models advocated in the EFLM CC in case of measurands with well-defined biological and clinical characteristics, as PG. Additional studies are necessary to determine the clinical impact of the TEa.

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Clinical Studies - Outcomes

Cod: T064

IMPACT OF MEASUREMENT ERROR OF PLASMA GLUCOSE ON CLINICAL CLASSIFICATION: A SIMULATION ANALYSIS

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BACKGROUND: According to EFLM Consensus Conference criteria on allocation of laboratory tests to the proper model to derive analytical performance specifications, the outcome-based model is well suited for fasting plasma glucose (PG), since the test is central to diagnose diabetes mellitus (DM) and to define glycaemic-related conditions. We previously described an indirect outcome model for the definition of allowable total error (TEa) of PG measurement. Here, we performed a simulation analysis to investigate the impact of derived TEa (±6.38%) on the clinical classification of the outpatient population served by our institution.
METHODS: We retrospectively retrieved PG results from outpatients for a 6-month period. PG was measured by a well-standardized and precise hexokinase assay on the Abbott Architect c16000 platform [average CV <1.3% and virtually unbiased (+0.2%) when compared with the CDC reference procedure]. The rate of subjects with impaired fasting PG (IFG), misclassified as frank DM or normoglycaemic if PG would be measured with a TEa of ±6.38%, was investigated.
RESULTS: The clinical classification of retrieved subjects [n=6537; median PG, 109 mg/dL; interquartile range (IQR): 99-128)] was 51.6% as healthy, 21.6% as IFG and 26.8% as DM. A +6.38% TE in PG measurement (median PG, 116 mg/dL; IQR: 105-136) resulted in +7.7% of subjects misdiagnosed as DM and +18.1% of healthy individuals classified as IFG. Conversely, a –6.38% TE (median PG, 102 mg/dL; IQR: 93-120) implied the shift of 6.2% DM to IFG category and of 12.6% IFG to the healthy group.
CONCLUSIONS: IFG represents a category at increased risk to develop DM. In this condition, the prevention of DM onset as well as of vascular hyperglycaemia-related complications is accomplished with interventions lowering PG over time. False negatives, i.e., IFG subjects misclassified as normoglycaemic, are therefore the most impacting results. In our served population, measuring PG with a TEa of ±6.38% theoretically implies that 12.6% of individuals would miss interventions necessary to stop the progression to DM and the worsening of related outcomes. Further clinical and economical evaluation is required to show if this misclassification rate is acceptable or a more stringent TEa should be applied.

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Clinical Studies - Outcomes

Cod: T065

SPUTUM TRANSPORTATION – NEW DATA REGARDING SHIPMENT CONDITIONS (DURATION AND TEMPERATURE) AND INFLUENCE OF THOSE PARAMETERS ON SAMPLE VIABILITY

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BACKGROUND:
The study was performed to measure the impact of temperature conditions and shipment duration on the viability of the sputum samples.
The classic approach is to transport the sputum samples as soon as possible to the laboratory, usually in max. 2 h in ambient conditions, due to the loss of some of the most sensitive pathogens as H. influenzae, H. parainfluenzae and Str. pneumoniae

METHODS:
Sputum samples from five regions from Romania, placed at various distances to Synevo Central Lab, were collected in sterile containers and shipped in max. 12 h to SCL refrigerated using gel-packs. Samples were collected from patients with non–cystic fibrosis bronchiectasis. The temperature was monitored with thermo-loggers. Gram stain smears and Gram stain were used for sputum sorting.Only proper sputum samples were plated, incubated, and bacteria were identified using Maldi Biotyper Brucker.

RESULTS:
Between March 2015 and October 2016, 452 sputum samples were received, 44 samples (9.73%) were rejected as saliva or saliva contaminated and 260 samples (57.52%) were positive. Pathogens identified in those samples were: Haemophilus influenzae (9.62%), Haemophilus parainfluenzae (7.69%), Moraxella catharrhalis (1.54%), Pseudomonas aeruginosa (59.23%), Staphilococcus aureus (13.85%), Stenotrophomonas maltophilia (1.15%), Streptococcus pneumoniae (6.92%).
Negative samples were 148, on all of the plates growing non-pathogen microflora.
Shipping temperature was between 3-8 C, with a mean temperature of 6.2 C.

CONCLUSIONS:
1. All the sputum samples transported in refrigerated conditions were viable
2. Temperature was not a factor for sample rejection
3. A 12 h duration for shipping ensure samples viability
4. Sensible species as Haemophilus influezae, H. parainfluenzae and Streptoccocus pneumoniae were identified in 24.23% of the sputum samples, a normal percentage of recovery

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Clinical Studies - Outcomes

Cod: T066

ROLE OF S100B AND NSE SERUM LEVELS IN PATIENTS SUFFERING FROM SPONTANEOUS INTRACEREBRAL HEMORRHAGE

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Background: Spontaneous intracerebral hemorrhage (ICH) is the second most common cause of stroke, preceded by ischemic stroke. It has an estimated incidence rate of 33 cases per 100,000 inhabitants. Despite advances in ICH patients' clinical management, up to date, its mortality remains very high: almost 50% die within 48 hours of the hemorrhage and just 12-39% of survivors result functionally independent. Several research studies conducted in the area of brain damage have analyzed to role of different proteins as biomarkers to identify the extension of damage or even to predict outcome. Two of the most promising in this field are S100B and neuron-specific enolase (NSE). The aim of this study was to evaluate the role of S100B and NSE serum levels in ICH patients.

Methods: 21 patients with ICH diagnosis admitted to the Neurosurgical Intensive Care Unit (ICU) of the Virgen del Rocío University Hospital were included in the study. Venous blood samples were drawn on admission and on subsequent 24, 48 and 72 hours. Clinical variables recorded included: Glasgow Coma Scale (GCS), Acute Physiology and Chronic Health Evaluation (APACHE), Modified intracerebral hemorrhage (MICH), Intracerebral hemorrhage (ICH) scores, and hemorrhage volume in the CT scan.

Results: There was a gradual decrease in S100B serum levels from the first to the fourth sample: admission=0.521 µg/L [IQR 0.286-1.158], 24h=0.431 µg/L [IQR 0.200-0.700], 48h=0.238 µg/L [IQR 0.137-0.446], 72h=0.212 µg/L [IQR 0.105-0.359]; ($p<0.001$). In reference to NSE values, we just observed a difference between 24h (14.27 µg/L [IQR 9.92-18.06]) and 48h (15.71 µg/L [IQR 11.46-23.53]) samples ($p=0.043$). When analyzing biomarker results based on intrahospital mortality, we found that patients who early died, had higher values of both S100B (death: 0.453 µg/L [IQR 0.178-0.770] vs. survival: 0.206 µg/L [IQR 0.128-0.305]; $p=0.045$) and NSE (death: 24.13 µg/L [IQR 12.01-25.83] vs. survival: 12.99 µg/L [IQR 9.29-17.65]; $p=0.036$) at 48h. Additionally, the measured biomarker levels correlated with the hemorrhage volume in the CT scan (S100B 24, 48 and 72h, NSE 72h) and with scores from the scales GCS (S100B admission), APACHE (NSE admission), MICH (S100B admission, 24, 48 and 72h, NSE 72h) and ICH (NSE admission).

Conclusions: These preliminary results demonstrate that S100B and NSE levels correlate with ICH patient severity as well as they are associated with early mortality.

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Clinical Studies - Outcomes

Cod: T067

STUDY OF CLEANING SOLUTION STABILITY BY USING OF URINE TEST STRIPS AND SPECTROPHOTOMETER

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The aim of this study was to find out the solution stability that is used as cleaning solution (cleaner) for HPLC analyzer (Hb-Vario) for the determination of glycated hemoglobin in whole blood. The Cleaner contents a bioactive agent, a proteolytic enzyme Savinase, which degrades hemoglobin and helps to purify of the analyzer. For this reason, it was necessary to perform a detailed stability study and find out the minimum activity that is still enough for degradation of hemoglobin. The minimum amount of Savinase in the cleaner was determined by using of spectrophotometer and the spectral change at 535 nm and 600 nm. The activity of Savinase was determined by using of urine test strips with Leuco-zone that is sensitive for Savinase. The strips were evaluated with urine analyzer.

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Clinical Studies - Outcomes

Cod: T068

LOW LEVELS OF 25-OH VITAMIN D IN WOMEN WITH ENDOMETRIOSIS AND ASSOCIATED PELVIC PAIN

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Endometriosis is a chronic disease often associated with pelvic pain and infertility. Recently, it has been shown that vitamin D plays an important role in the physiological functions of the reproductive system. Conflicting data have been reported on the relationship between endometriosis and vitamin D. The aim of the present prospective observational cohort study was to analyze the correlation between the levels of 25-OH Vitamin D and endometriosis and associated symptoms.25-OH Vitamin D serum levels (normal value ≥ 30 ng/ ml) have been analyzed in 104 women with surgically confirmed endometriosis. Pain symptoms, fertility and CA125 values of all patients were evaluated and recorded. Intensity of pain was measured by the means of 10- points Visual Analogue Scale (VAS). Correlation between vitamin D levels and presence of endometriosis, pain, infertility and CA125 levels was analyzed. Insufficient 25-OH Vitamin D levels were found in 80% of women with endometriosis; this association was statistically significant ($p<0.001$). Low levels also correlated with the presence of moderate/ severe pain < 5 at VAS ($p< 0.02$) and high levels of CA125 ($p< 0.03$). No correlation was found with infertility and other evaluated factors. The results of this study highlight the role of 25-OH Vitamin D as a possible modifiable risk factor for endometriosis and its symptoms, although a cause-effect relationship is not clear. Further studies are needed to confirm this association. Vitamin D supplementation could be suggested in selected patients with insufficiency of the vitamin associated with symptomatic endometriosis

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Clinical Studies - Outcomes

Cod: T069

PROMOTER METHYLATION STATUS OF BRCA1 AND BRCA2 IN WOMEN CONSUMING ORAL CONTRACEPTIVES

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Background- Oral contraceptives (OC) convey a protection against ovarian, endometrial and perhaps colorectal cancer. Evidence suggests that recent OC use is associated with an increased breast cancer risk. Hypermethylation of the promoter has been proposed as one mechanism for functionally inactivating of BRCA1 and BRCA2 tumor suppressors. This study was designed to estimate the effect of OC use on Promoter Methylation Status of BRCA1/2.
Materials and Methods- Methylation of the genomic BRCA1 and BRCA2 promoters was studied using methylation-specific PCR (MSP) in peripheral blood of 38 women OC users compared to control group. The frequency of the methylation for each gene was analyzed by chi-square method
Results- Overall, promoter hypermethylation frequencies observed were: 71% for BRCA1 and 84% for BRCA2 that showed the prevalence of promoter hypermethylation was higher in OC user in compare with control group that were 36% and 50% respectively.
Conclusion- These data suggest that OC consumption may be associated with changes in specific promoter hypermethylation and oral contraceptives may contribute in relatively high incidence of breast cancers.