

research where there is exposure to background radiation and no therapeutic benefit to participants.

Methods The ethical and regulatory issues encountered in the ERA-NET PRIOMEDCHILD project 'Paediatric Accelerator Mass Spectrometry Evaluation Research Study (PAMPER)' were analysed. These included the project design, scientific and ethical reviews, informed consent and recruitment processes. Infants 0–2 years were recruited in Estonia and the UK to study the pharmacokinetics (PK) of acetaminophen using accelerator mass spectrometry (AMS) bioanalysis. The study was considered in the context of the scientific, regulatory, and ethical frameworks guiding Phase 0 studies in adults and children.

Results The science and ethics were developed in the protocol design and informed consent process, which resulted in approval of the study by research ethics committees in the UK and Estonia. Fifty-two babies were recruited into the study, with an acceptance rate of 50% among the parents approached. The study results demonstrated PK comparability between microdosing and therapeutic dosing in young children.

Conclusions The PAMPER study showed the feasibility and validity of microdosing AMS PK studies in children. This methodology may provide a safer and more ethically robust approach for paediatric PK studies in certain drug models than more traditional PK study designs. The parameters and validation methods for microdosing AMS PK studies need to be reflected in regulatory guidance from the EMA, FDA and other authorities.

Intensive Care I

PS-129 CONTINUOUS SUBCUTANEOUS GLUCOSE MONITORING (CGM) DURING PAEDIATRIC CRITICAL CARE

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10.1136/archdischild-2014-307384.424

Background and aims The last decade gave clear evidence that hyper/hypoglycemia and glucose variability are associated with increased mortality in critically ill patients. Continuous glucose monitor (CGM) is a new device in paediatric critical care units (PICU) with clear advantages in glucose monitoring. The aim of our study was to survey the incidence of glucose regulation disorders in our PICU and specify the association between the PRISM III score and the glycemic variability [mean amplitude of glycemic action (MAGE)].

Methods We evaluated 22 children: mean age: 1.3 years, mean length of PICU stay: 18 days; 20/22 patients were on invasive mechanical ventilation; 6/22 needed vasoactive agent therapy. CGM duration: 1–12 days. Interstitial glucose level was monitored by Guardian[®] REAL Time CGM (Medtronic[®]). Reference glucose values were obtained from blood gas analyzer or point-of-care glucose analyzer. We used Spearman correlation to evaluate the association between PRISM III and the MAGE.

Results Hypo- and hyperglycemia (CGM glucose < 55 mg/dl / CGM glucose > 180 mg/dl) were detected in 4.6% and 2.5% of measurements, respectively. The mean MAGE (meaningful excursion >45 mg/dl) and PRISM III were 78 mg/dl and 19. We found a significant correlation between PRISM III and MAGE ($r = 0.55$; $p < 0.05$). Pearson's correlation coefficient (0.82) and Clarke Error Grid analysis (96% clinical accuracy) proved a good reliability of the CGM.

Conclusions Glucose homeostasis disorders are frequent in the PICU; hypoglycemia being more commonly detected. Increased PRISM III score contributes significantly to the elevation of glucose variability.

PS-131 HEMOLYSIS IN NEONATAL PIGLETS RECEIVING CENTRIFUGAL-PUMP EXTRACORPORAL RESPIRATORY SUPPORT: AN IN-VIVO COMPARATIVE BENCH STUDY

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10.1136/archdischild-2014-307384.425

Background The challenge of non-cardiac, neonatal extracorporeal membrane oxygenation (ECMO) is the need for miniaturised circuits, small cannulas and low flow rates. Novel small rotating pump devices with diagonal blood flow have a reduced priming volume and circuit surface area. Bench studies in different in-vitro models are encouraging. However, little data exist on hemolysis, coagulation and fibrinolysis in defined in-vivo models.

Setting Twelve newborn piglets were randomly assigned to receive either veno-arterial ECMO with a novel diagonal pump system or to serve as controls. The ECMO circuit was pre-filled with 70 ml packed red blood cells from adult swine. Blood was drained through 8 Fr venous and reinfused through 6 Fr arterial cannulas. ECMO was applied on 75% total cardiac output (80–100 ml/kg). The effect of the diagonal pump system on required circuit settings, heparin-use, plasma-free haemoglobin (fHb), lactate dehydrogenase and coagulation/fibrinolysis were studied.

Results Mild hemolysis was diagnosed within the first hour in all ECMO-piglets [mean fHb 49.7 mg/dl [9.0; 90.3; 95% CI]. After 8 hrs on ECMO mean fHb decreased, but was still significantly higher as compared to controls (25.5 mg/dl [8.7; 42.5] vs 4.7 mg/dl [0.8; 8.6], $p = 0.02$). Median mean flow rate, venous inlet pressure, and revolutions per hour were 222 ml/min (197; 313, Range), -20 cm H₂O (-36; -6), and 5295 rpm (4906; 6816) respectively. Fibrin degradation products and fibrinogen levels remained normal in ECMO and control piglets throughout the study period.

Conclusion The use of a novel diagonal pump system for ECMO in our in-vivo model generates a comparable amount of fHb as previously observed under in-vitro conditions.

PS-132 IMPACT OF STANDARDISED CONCENTRATIONS ON DRUG INFUSION PROCESS IN NICU/PICU: A SIMULATION STUDY FROM PRESCRIPTION TO ADMINISTRATION

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10.1136/archdischild-2014-307384.426

Background and aims Transition to standardised concentrations (StdC) is advised to reduce risks with IV infusions in PICU/NICU. In our unit, infusion rate is standardised and concentration varies (VarC). We performed a simulation study to evaluate the impact of StdC on prescription, preparation and administration.