Neonatal Adaptation

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Background

Neonatal circulatory failure is a unique condition which can affect up to 50% of all infants admitted to NICU.1,2 The acute consequences can lead to intraventricular haemorrhages which can in turn lead to cerebral palsy a condition that has a great impact on patients, their families and society.1-2 Many of the treatments, such as dopamine, lack evidence in the treatment of this condition, but also around 70-80% of drugs used in the neonatal population are unlicensed.3 This is an under-researched within the field of neonatology with a number of unanswered questions. The NEO-Circ and the Neo-Adapt projects aim to answer some of these dilemmas though:

- Developing an evidence based definition of circulatory failure
- Researching novel and non-invasive biomarkers to monitor an infants cardiovascular health4,5
- Developing a licenced neonatal formulation of dobutamine6. Evidence indicates that dobutamine may improve neurological outcome in infants with circulatory failure as well as other parameters such as gut perfusion7,8,9

The NEO-Circ and the Neo-Adapt Projects

NEO-Circ 1: Exploratory therapeutic trial with dobutamine pharmacokinetic and pharmacodynamic sub studies

NEO-Circ 2: Dobutamine dose finding study

NEO-Circ 3: Large randomised controlled trial for the use of dobutamine in neonatal circulatory failure

NEO-Circ 4: Systematic review of the use of dobutamine in neonates and children

NEO-Adapt 1, 2 & 3: Prospective cohort studies exploring novel reference values for non invasive biomarkers of cardiovascular health in neonates aged >3 weeks gestational age who are well, receiving intensive care and therapeutic total body cooling. This will include dobutamine pharmacokinetic and pharmacodynamic sub study’s

Funding

- 2011-2016 FP7-Single stage-Health Grant €5,99 million. Dobutamine for NEOnatal CIRCulatory failure defined by novel biomarkers (PD Dr Heike Rabe on behalf of an international consortium)
- 2013-2016 PhD studentship £ 125198 (Partly funded by a FP7 grant & by the Rockinghorse Appeal)

NEO-Circulation Consortium

The consortium includes international experts from 8 countries in neonatal medicine, pharmacology, pharmacogenomics, drug formulation and pre-clinical neonatal models and an experienced group of experienced multicentre clinical trials NICU’s.

References

3. Rabe H: Ethical aspects of the new EU pharmacodynamic and pharmacokinetic sub study’s