Journal of Neonatal Nursing (2014) **20**, 147—153

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NEWS ON RESEARCH

Neonatal research update

Established at the University of Oxford in 1978, the mission of the NPEU is: *to produce methodological rigorous research evidence to improve the care provided to women and their families during pregnancy, childbirth, the newborn period and early childhood as well as promoting the effective use of resources by perinatal health services.*

NPEU operates as an integrated research unit comprised of three broad entities: the Clinical Trials Unit, Policy Research in Maternal Health and Care, and Epidemiological and Health Services Research.

Our work involves running randomised controlled trials, national surveillance programmes and surveys, confidential enquiries, aetiological studies and a disease register. The results of our research sit at the nexus of public and population health sciences, clinical care and health policy development.

- For full details of the Unit's activities, visit www.npeu.ox.ac.uk
- Telephone 01865 289700, email: ctu@npeu.ox.ac.uk
- Follow us on Twitter: https://twitter.com/npeu_ctu
- See videos at the NPEU You Tube channel at www.youtube.com/NPEUOxford

Randomised Controlled Trials (RCTs) make up a large component of the NPEU's work. The ongoing programme of trials evaluates a broad range of interventions for women and babies in the perinatal health services. These are typically large multi-centre trials, involving many hospitals both nationally and sometimes internationally.

The NPEU Clinical Trials Unit (NPEU CTU) is a UK Clinical Research Collaboration (UKCRC) fully registered Clinical Trials Unit (www.ukcrc-ctu.org.uk) and is part of the consortium leading the NIHR Clinical Research Network (CRN): Children — formerly NIHR Medicines for Children Research Network (MCRN www.mcrn.org.uk), set up to improve the co-ordination, speed and quality of RCTs and other well designed studies of medicines for babies, children and adolescents.

The NPEU Clinical Trials Unit aims to:

- Design, develop, organise and conduct large multi-centre pragmatic RCTs, which assess the clinical and cost effectiveness of interventions on important and, ideally, substantive outcome measures
- Support other researchers in the UK and overseas in the design, development, conduct and analysis of RCTs in the perinatal field
- Develop methodology to improve the understanding and promote the undertaking of innovative RCTs
- Disseminate results of RCTs to clinicians and participants to facilitate evidence-based best practice and improve the care provided by the NHS

The National Institute for Health Research Clinical Research Network Portfolio (NIHR CRN

http://dx.doi.org/10.1016/j.jnn.2014.05.007
1355-1841

Portfolio) studies are those which are funded or supported by the Department of Health through the National Institute for Health Research. Many of the studies based at NPEU are included within the portfolio; this is indicated where applicable and they are not listed again in the NIHR CRN section of this report.

Additional information and contact details for the NPEU Clinical Trials Unit and each trial (including up-to-date recruitment figures) can be found on the respective NPEU web pages, accessible from www.npeu.ox.ac.uk/trials. Protocols and data collection forms for all NPEU CTU-run trials are available on their respective websites.

For trials-related telephone enquiries please call Ann Kennedy on 01865 289728 or email ctu@npeu.ox.ac.uk

NPEU CTU neonatal trials update

Trials in set-up (May 2014)

Baby OSCAR — *in set-up*
Outcome after **S**elective Early Treatment for **C**losure of Patent Ductus **AR**teriosus in Preterm Babies

Objectives: To determine if selective early treatment of echocardiography confirmed large PDAs in extremely preterm babies with ibuprofen within 72 h of birth reduces the incidence of death or moderate or severe bronchopulmonary dysplasia (BPD) at 36 weeks postmenstrual age, with improvement to short and long term clinical and health economic outcomes. Masked randomised placebo-controlled trial; funded by the NIHR Health Technology Assessment Programme.

NIHR CRN Portfolio Study.

Target recruitment: 730 preterm infants at 25 tertiary centres; an internal pilot study is planned, prior to roll-out nationwide.

Trials open to recruitment (May 2014)

ELFIN — *recruiting*
Enteral **L**acto**F**errin **I**n **N**eonates

A multi-centre randomised placebo controlled trial of prophylactic enteral supplementation with bovine lactoferrin to prevent late-onset invasive infection in very preterm infants.

Primary research question: the study aims to determine whether infants born very preterm (before 32 weeks' gestation) who receive supplemental lactoferrin have a lower incidence of late-onset (occurring more than 72 h after birth) infection than a placebo group.

NIHR CRN Portfolio Study.

Funded by the NIHR Health Technology Assessment Programme; Target recruitment: 2,200 across 30 centres.

SIFT — *recruiting*
Speed of **I**ncreasing milk **F**eeds **T**rial

A multi-centre randomised controlled trial of two speeds of daily increment of milk feeding in very preterm or very low weight infants.

Primary research question: To assess and compare the effects of a fast (30 ml/kg/day) and a slow (18 ml/kg/day) increase in milk feed volumes on survival of very preterm (<32 weeks) or very low birth weight (<1,500 g) infants without moderate or severe disability at 24 months of age corrected for prematurity

NIHR CRN Portfolio Study.

Funded by the NIHR Health Technology Assessment Programme; Target recruitment: 2,500 infants from 60 neonatal units within the UK and Ireland over 3 years.

TOBY Xe Study: Neuroprotective effects of hypothermia combined with inhaled xenon following perinatal asphyxia — *recruiting*
Hypothesis. *Following perinatal asphyxia treatment with a combination of hypothermia and inhaled xenon preserves cerebral metabolism and structure*.NIHR CRN Portfolio Study.Funded by Medical Research Council. Safety and feasibility study. Currently recruiting until mid-2014, target recruitment 130; no new recruiting centres required.

Trials in follow-up (May 2014)

I2S2 — *follow-up in progress*
Iodine Supplementation in Preterm Infants

Primary research question: does iodine supplementation of extremely preterm infants improve neurodevelopment outcome at 2 years corrected age?

This study aims to determine whether nutritional supplementation with iodide, compared with non-supplementation, will enable extremely preterm infants to achieve a positive iodide balance and whether this protects brain development in this group of infants. Follow-up of participants at 2 years of age; follow-up phase started in June 2012, due for completion in June 2015.