



NEWS ON RESEARCH

Neonatal research update

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NPEU Clinical Trials Unit

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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.

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- 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 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 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, data collection forms and all other documentations 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 (January 2015)

Baby OSCAR

To determine if the selective treatment of confirmed large Patent Ductus Arteriosus (PDA) in extremely preterm babies with ibuprofen within 72 h of birth, reduces the incidence of death or bronchopulmonary dysplasia (BPD) at 36 weeks' postmenstrual age.

The study title is: Outcome after Selective Early Treatment for Closure of Patent Ductus Arteriosus in Pre-term Babies, or Baby-OSCAR in short.

NIHR CRN Portfolio Study.

Funded by The NIHR Technology Assessment Programme; this is an investigator-led, non-commercial trial sponsored by the University of Oxford.

The trial aims to recruit approximately 730 babies over 45 months from participating neonatal units across the UK. Initially, the study will be piloted in 4 neonatal units and later rolled out to

other units pending the success of the pilot phase. Recruitment is planned to start in Spring 2015.

Trials open to recruitment (January 2015)

ELFIN

Enteral LactoFerrin In Neonates

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: 2200 across 30 centres. Current recruitment total: 42.

SIFT

Speed of Increasing milk Feeds Trial

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 (<1500 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: 2800 infants from 60 neonatal units within the UK and Ireland. Current recruitment total: 2077.

PHOENIX

Pre-eclampsia in Hospital: Early Induction or Expectant Management

A multi-centre randomised controlled to determine whether delivery in women with pre-eclampsia between 34 + 0 and 36 + 6 weeks of gestation reduces maternal complications without short and long term detriment to the infant compared to expectant management and delivery at 37 weeks of gestation.

Relevant outcomes of interest to neonatal units.

NIHR CRN Portfolio Study.

Funded by the NIHR Health Technology Assessment Programme; Target recruitment: 900 across 25 centres.

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