



NEWS ON RESEARCH

Neonatal research update

NPEU Clinical Trials Unit
National Perinatal Epidemiology Unit, University
of Oxford



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

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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 (CTU) is a UKCRC Registered Clinical Trials Unit and is part of the consortium leading the NIHR Medicines for Children Research Network (MCRN), set up to improve the co-ordination, speed and quality of RCTs and other well designed studies of medicines for babies, children and adolescents. In addition, the NPEU CTU supports the National Reproductive Health Research Network (NRHRN), which is hosted and facilitated by the Royal College of Obstetricians and Gynaecologists and includes an increasing number of Clinical Study Groups.

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.

NPEU CTU neonatal trials update

Trials in set-up (December 2013)

ELFIN – *in set-up*

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.

Baby OSCAR – *in set-up*

Outcome after Selective Early Treatment for Closure of Patent Ductus ARteriosus in Pre-term Babies

Objectives: To determine if selective early treatment of echocardiography confirmed large PDAs in extremely pre-term babies with ibuprofen within 72 h of birth reduces the incidence of death or bronchopulmonary dysplasia (BPD) at 36 weeks post-menstrual 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. Target recruitment: 730 pre-term infants at 25 tertiary centres, no new sites required.

Trials open to recruitment (December 2013)

SIFT – *recruiting*

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: 2500 infants from approximately 30 neonatal units within the UK and Ireland over 3 years.

Trials in follow-up (December 2013)

BOOST-II UK – *follow-up in progress*

The Benefits of Oxygen Saturation Targeting

Primary research question: BOOST-II UK is a double blind randomised controlled trial to compare the effects of targeting arterial oxygen saturations at levels of 85–89% versus 91–95% in babies born at less than 28 weeks' gestation. The composite primary outcome for the trial is mortality and major disability at age 2 years (corrected for prematurity).

NIHR CRN Portfolio Study

Funded by Medical Research Council. Target recruitment 1200, actual recruitment 973. Follow-up at 2 years of age, in progress. Short-term outcomes published online in May 2013, in the New England Journal of Medicine: <http://dx.doi.org/10.1056/NEJMoa1302298>.

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?

NIHR CRN Portfolio Study

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.

Funded by NIHR Evaluation, Trials and Studies Co-ordinating Centre; Efficacy and Mechanism Evaluation Programme (NETSCC EME); recruited 1275 infants at 21 centres. Follow-up of participants at 2 years of age; follow-up phase started in June 2012, due for completion in June 2015.

Trials in analysis, pending publication and dissemination (December 2013)

PiPS – *in analysis*

Probiotics in Preterm babies Study

Hypothesis: early administration of B breve BBG to preterm infants reduces the incidence of episodes of infection, necrotising enterocolitis and death.

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