



## The neoGASTRIC Trial

Avoiding routine gastric residual volume measurement in neonatal critical care. A multicentre, pragmatic, unblinded, 2-arm, parallel group, opt-out, randomised controlled trial, with an internal pilot (and embedded process evaluation), and an integrated health economic analysis.

## WHY?

To determine whether avoiding the routine measurement of gastric residual volumes in preterm infants less than 34 weeks' gestation reduces the time taken for an infant to reach full enteral feeds without increasing harm.

## WHO?

7040 infants will be recruited across hospitals in the UK and Australia, who fulfil the following eligibility criteria:

Inclusion criteria:

- Gestational age at birth less than 34<sup>+0</sup> gestational weeks<sup>+days</sup>
- Nasogastric or orogastric tube in place

## Exclusion criteria:

- Infant has received more than 15 ml/kg/day of milk for more than 24 hours
- Gastrointestinal surgical condition prior to randomisation
- Major congenital abnormalities
- No realistic prospect of survival
- A parent has opted out of infant's participation in neoGASTRIC

## WHAT?

Two standard care pathways will be compared:

- 1. No routine measurement of gastric residual volumes, and
- 2. Routine, up to 6 hourly, measurement of gastric residual volumes

The allocated care pathway will be followed:

- for as long as routine gastric residual volume measurement is standard local practice or.
- gastric feeding tubes are no longer required or,
- the infant is discharged home or,
- the infant reaches 44<sup>+0</sup> gestational weeks<sup>+days</sup>

## WHEN?

The duration of the trial is 50 months (including a 12 month internal pilot and a total of 36 months recruitment), with recruitment starting in 2023.

## HOW?

The neoGASTRIC trial is funded by the NIHR and the NHMRC and is NIHR portfolio adopted. The trial will be coordinated separately for UK and AU sites with dedicated trial management teams:

- National Perinatal Epidemiology Unit Clinical Trial Unit (NPEU CTU), University of Oxford, Oxford, England.
- Monash Newborn, Monash Children's Hospital, Monash Health, Clayton, Australia.

GUIDANCE

# The neoGASTRIC Trial: Avoiding routine gastric residual volume measurement in neonatal

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## Randomisation (1:1 allocation ratio)

critical care

Secure online randomisation

## NO ROUTINE MEASUREMENT OF GASTRIC **RESIDUAL VOLUMES**

**ROUTINE - UP TO 6 HOURLY -**MEASUREMENT OF GASTRIC RESIDUAL **VOLUMES** 

The allocated care pathway will be followed for as long as routine gastric residual measurement is standard local practice, until gastric feeding tubes are no longer required, the infant is discharged home or reaches 44<sup>+0</sup> gestational weeks<sup>+days</sup> (whichever is sooner)

Where possible trial data will be extracted from the electronic patient records Follow-up and evaluation of outcomes will be up to discharge home or 44<sup>+0</sup> gestational weeks<sup>+days</sup> (whichever is sooner), unless otherwise stated.

Time from birth to reach full milk feeds for 3 consecutive days (at least 145 ml/kg/day where this is considered full enteral feeds, or where breastfeeding and any additional milk is considered equivalent to full enteral feeds).

## Key secondary outcome

Necrotising enterocolitis, modified Bell's stage 2 or greater

## Other secondary outcomes

- · Severe necrotising enterocolitis, confirmed at surgery or leading to death
- All-cause mortality
- · Focal intestinal perforation
- · Gastrointestinal surgery
- · Late-onset infection: microbiologically-confirmed or clinically suspected infection >72 hours after birth
- Duration of neonatal unit stay
- · Duration of any parenteral nutrition
- · Duration with a central venous line in situ
- · Weight standard deviation score
- · Head circumference standard deviation score
- · Duration of invasive ventilation
- · Chronic lung disease

- · Retinopathy of prematurity treated medically or surgically
- · Brain injury on imaging: intraventricular haemorrhage grade 3 or 4 and/or cystic periventricular leukomalacia
- Any vomiting resulting in feeds being withheld, up to 14 days from randomisation
- · Number of days feeds withheld at least once, up to 14 days from randomisation
- Total number of hours feeds withheld, up to 14 days from randomisation
- Breastfeeding at discharge home or 44<sup>+0</sup> gestational weeks\*days (whichever is sooner)
- · Receiving maternal breastmilk at discharge home or 44<sup>+0</sup> gestational weeks<sup>+days</sup> (whichever is sooner)

## Health economic outcomes

- · Number of gastric residual volume measurements
- · Abdominal x-ray investigations
- Antibiotic use, and surgery for necrotising enterocolitis or focal intestinal perforation
- · Healthcare costs

neoGASTRIC trial flow chart 17:03:23

# CONTACT

For all queries please contact the Trial Coordinator Centre, National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) via Email: neogastric@npeu.ox.ac.uk or via Telephone: 01865 617927.

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