

1. NeoGASTRIC Trial Summary

The neoGASTRIC Trial

Avoiding routine gastric residual volume measurement in neonatal critical care. A multi-centre, 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⁺⁰ gestational weeks^{+days}
- 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⁺⁰ gestational weeks^{+days}

WHEN?

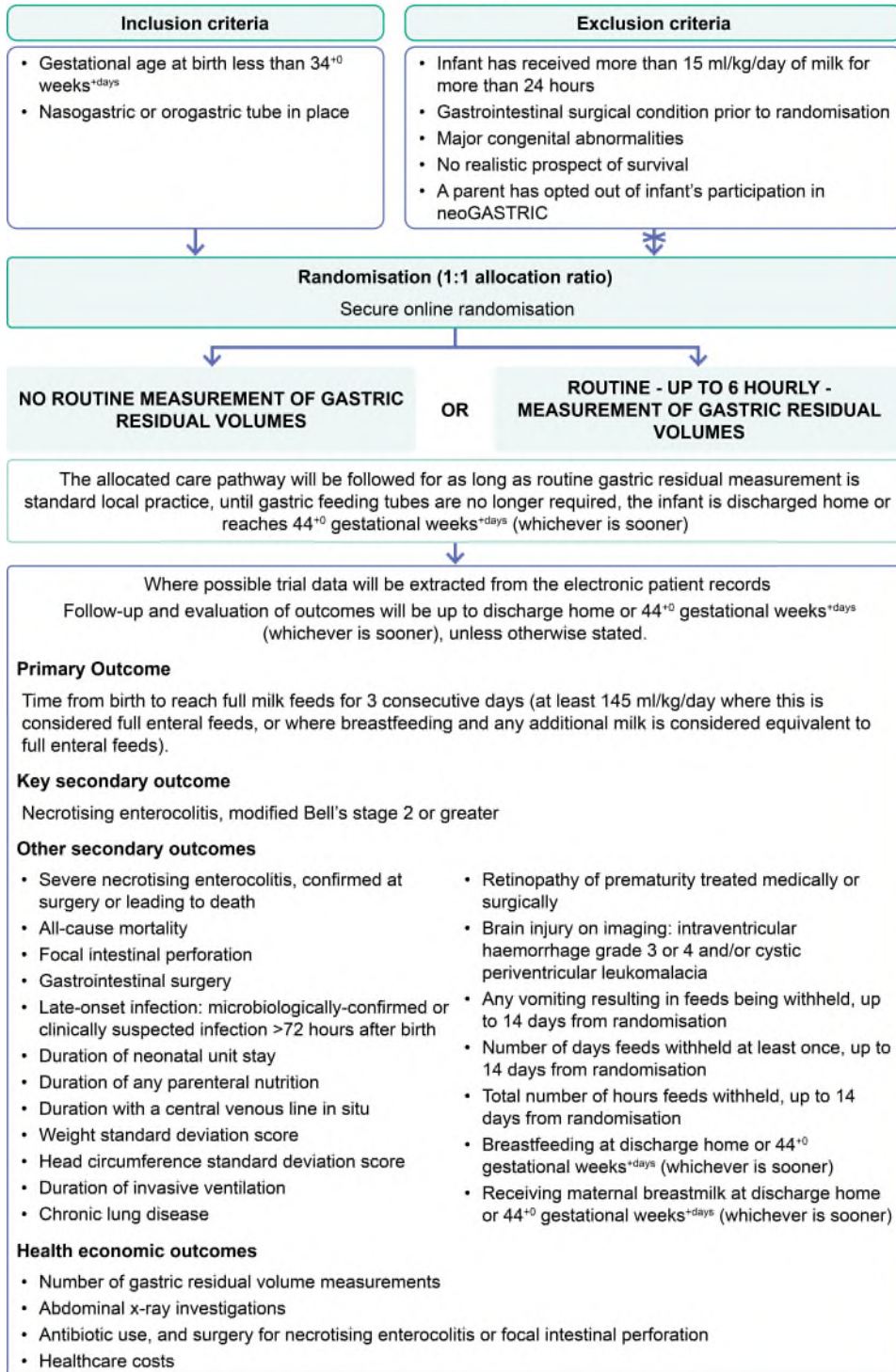
The duration of the trial is 50 months (including a 12 month internal pilot and a total of 36 months recruitment), with recruitment starting in 2023.

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.

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neoGASTRIC trial flow chart 17.03.23

CONTACT

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