The neoGASTRIC trial: Avoiding routine gastric residual volume measurement in neonatal critical care

Submission date	Recruitment status Recruiting	[X] Prospectively registered		
25/01/2023		[X] Protocol		
Registration date	Overall study status Ongoing Condition category Neonatal Diseases	Statistical analysis plan		
08/02/2023		Results		
Last Edited		Individual participant data		
08/01/2025		[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

About one in seven babies born in the UK each year need specialist neonatal care in a hospital because they are born too early, are born very small or have a medical condition. Ensuring these babies have enough nutrition is a key part of their care.

Premature babies are fed milk every few hours through a soft plastic tube via their nose or mouth into their stomach, called a gastric tube. As premature babies stomachs and digestive systems are not yet ready for lots of milk, the amount of milk given each feed is increased slowly. Some doctors and nurses regularly check how much milk is left in a baby's stomach, called 'routinely measuring gastric residual volumes'. They check because they believe it will help them know how the baby is coping with the milk feeds and they also think it may help to identify a severe disease called necrotising enterocolitis (NEC). However, others think that measuring gastric volumes may be bad for babies and that it is inaccurate, uncomfortable for the baby and may actually be harmful.

The aim of the neoGASTRIC trial is to see if premature babies can safely get to full milk feeds quicker.

Who can participate?

All babies that are born 6 or more weeks early (before 34 weeks of pregnancy) who require tube feeding. The neoGASTRIC study is an opt-out study. Therefore all eligible babies will take part unless a parent does not wish their baby to participate or there is a medical reason why.

What does the study involve?

The neoGASTRIC trial will involve babies born more than 6 weeks early and will recruit about 7000 premature babies across the UK and Australia. Babies will be recruited from about 36 hospitals in the UK and 3-4 large hospitals in Australia, and will be recruited into one of two groups: to have no routine gastric residual volumes measured, or have gastric residual volumes measured regularly. This will be decided by chance, and babies will have an equal chance of being in either group. The two approaches being compared are already used in clinical practice

across the UK and Australia, so there is nothing new about either type of care. Babies will stay in the study until they reach full feeds, get discharged home, or when they reach 4 weeks past their due date (whichever one comes first)

The NeoGASTRIC trial will use an opt-out consent process, designed to be as simple as possible for families. This means that babies meeting the eligibility criteria will be automatically included in the trial unless parents opt-out. Parents will be informed about neoGASTRIC through posters and leaflets on the neonatal units and will have the option to opt-out at any point. This will make it easier for parents to be involved in the research and involve families who might not normally take part in research.

What are the possible benefits and risks of participating?

Both clinical approaches being studied are currently routinely practiced in the UK and Australia and so we do not believe there are any additional risks or benefits of taking part in neoGASTRIC. Not routinely measuring gastric residual volumes might lead to babies reaching full feeds quicker which might reduce the risk of infections – but we will only know this after we finish the neoGASTRIC study. We do not think there will be a greater risk of necrotising enterocolitis (NEC) from not routinely measuring gastric residual volumes because countries which do not routinely do this, such as France, have similar amounts of necrotising enterocolitis in the UK. Doctors and nurses will continue to look for necrotising enterocolitis through standard care and regular checks.

Where is the study run from?

The National Perinatal Epidemiology Unit, Clinical Trials Unit (NPEU CTU) at the University of Oxford, England, UK, in partnership with Monash University, Australia are coordinating and managing the study on behalf of the sponsor, Imperial College London.

When is the study starting and how long is it expected to run for? September 2022 to October 2026

Who is funding the study?

The study is funded by the National Institute for Health and Care Research in the UK and the National Health and Medical Research Council in Australia.

Who is the main contact? Chris Gale, Chief Investigator, Christopher.gale@imperial.ac.uk Elizabeth Nuthall, Trial Manager, neogastric@npeu.ox.ac.uk

Contact information

Type(s)

Public

Contact name

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Type(s)

Principal investigator

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Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

321050

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 321050, CPMS 54912

Study information

Scientific Title

Among babies born <34+0 gestational weeks does no routine measurement of gastric residual volume compared to routine (up to 6 hourly) measurement of gastric residual volumes lead to faster establishment of full enteral feeds without an increase in necrotising enterocolitis (NEC)?

Acronym

neoGASTRIC

Study objectives

The neoGASTRIC trial is taking place 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, up until discharge home or 44+0 gestational weeks +days.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/02/2023, London Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8150; riverside.rec@hra.nhs.uk), ref: 23/LO/0060

Study design

Multi-centre randomized controlled trial

Primary study design

Other

Study type(s)

Other

Health condition(s) or problem(s) studied

Preterm birth

Interventions

The neoGASTRIC study is an individually randomised, controlled, unmasked, trial comparing two parallel care pathways, with an internal pilot and process evaluation.

The two care pathways to be compared are:

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

Both pathways represent standard clinical practice in different neonatal units in the UK and Australia.

Eligible infants will be identified by the neonatal teams in both the UK and Australia after admission. As both care pathways are standard neonatal practice, neoGASTRIC will use an optout consent approach.

The allocated 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+0 gestational weeks +days (whichever is sooner).

Updated 08/01/2025:

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

Randomisation of infants to either no routine measurement of gastric residual volumes or up to 6 hourly measurement of gastric residual volumes will be managed via a secure web-based randomisation facility hosted by the National Perinatal Epidemiology Unit Clinical Trials Unit (University of Oxford) with telephone backup available at all times (365 days per year).

Infants will be randomised using an online secure central randomisation service to ensure allocation concealment. The randomisation program will use a probabilistic minimisation algorithm and randomisation will use a 1:1 allocation ratio. To ensure balance between the randomised groups, minimisation criteria will include: hospital, multiple births and week of gestational age at birth.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Superiority outcome:

All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants' hospital notes/records.

1. neoGASTRIC main trial - superiority outcome

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).

Also including,

- 2. neoGASTRIC Process Evaluation primary outcome: to evaluate pilot phase trial processes by analysing parent and staff responses from questionnaires and observing staff practices.
- 3. neoGASTRIC SWAT primary outcome: the parent did not opt out of infant's participation in the trial pre-randomisation.

Key secondary outcome(s))

Updated 08/01/2025: Secondary outcome measures as of 13/06/2023:

All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants' hospital notes/records.

Key secondary outcomes (non-inferiority outcome):

Necrotising enterocolitis (NEC), modified Bell's stage 2 or greater, evaluated by blinded endpoint review committee.

Other secondary outcomes (superiority outcomes):

- 1. Severe NEC, confirmed at surgery or leading to death
- 2. All-cause mortality
- 3. Focal intestinal perforation
- 4. Gastrointestinal surgery
- 5. Late-onset infection: microbiologically-confirmed or clinically suspected infection >72 hours after birth, evaluated by blinded endpoint review committee. To note: this is the same that has been used in previous trials (e.g. SIFT, ELFIN)
- 6. Duration of neonatal unit stay
- 7. Duration of any parenteral nutrition
- 8. Duration with a central venous line in situ
- 9. Weight standard deviation score
- 10. Head circumference standard deviation score
- 11. Duration of invasive ventilation
- 12. Chronic lung disease
- 13. Retinopathy of prematurity treated medically or surgically
- 14. Brain injury on imaging: intraventricular haemorrhage grade 3 or 4 and/or cystic periventricular leukomalacia
- 15. Any vomiting resulting in feeds being withheld, up to 14 days from randomisation
- 16. Number of days feeds withheld at least once, up to 14 days from randomisation
- 17. Total number of hours feeds withheld, up to 14 days from randomisation
- 18. Breastfeeding at discharge home or 44+0 gestational weeks+days (whichever is sooner)
- 19. Receiving maternal breastmilk at discharge home or 44+0 gestational weeks+days (whichever is sooner)

neoGASTRIC SWAT secondary outcome is to evaluate the quality of parental decision making by using descriptive statistics.

Previous secondary outcome measures as of 13/06/2023:

All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants hospital notes/records.

Non-inferiority outcome:

1. Necrotising enterocolitis (NEC), modified Bell's stage 2 or greater, evaluated by blinded endpoint review committee.

Other secondary outcomes - Superiority outcomes

- 2. Severe NEC, confirmed at surgery or leading to death
- 3. All-cause mortality
- 4. Focal intestinal perforation
- 5. Gastrointestinal surgery
- 6. Late-onset infection: microbiologically-confirmed or clinically suspected infection >72 hours after birth, evaluated by blinded endpoint review committee. To note: this is the same that has been used in previous trials (e.g. SIFT, ELFIN)
- 7. Duration of neonatal unit stay

- 8. Duration of any parenteral nutrition
- 9. Duration with a central venous line in situ
- 10. Weight standard deviation score
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- 18. Breastfeeding at discharge home or 44+0 gestational weeks+days (whichever is sooner)
- 19. Receiving maternal breastmilk at discharge home or 44+0 gestational weeks+days (whichever is sooner)

neoGASTRIC SWAT secondary outcome is to evaluate the quality of parental decision making by using descriptive statistics.

Original secondary outcome measures:

All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants hospital notes/records.

Non-inferiority outcome:

1. Necrotising enterocolitis (NEC), modified Bell's stage 2 or greater, evaluated by blinded endpoint review committee.

Other secondary outcomes - Superiority outcomes

- 2. Severe NEC, confirmed at surgery or leading to death
- 3. All-cause mortality
- 4. Focal intestinal perforation
- 5. Gastrointestinal surgery
- 6. Late-onset infection: microbiologically-confirmed or clinically suspected infection >72 hours after birth, evaluated by blinded endpoint review committee. To note: this is the same that has been used in previous trials (e.g. SIFT, ELFIN)
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- 11. Head circumference standard deviation score
- 12. Duration of invasive ventilation
- 12. Chronic lung disease
- 13. Retinopathy of prematurity treated medically or surgically
- 14. Any vomiting resulting in feeds being withheld, measured up to 14 days from randomisation
- 15. Number of days feeds withheld at least once, measured up to 14 days from randomisation
- 16. Total number of hours feeds withheld, measured up to 14 days from randomisation
- 17. Breastfeeding at discharge home or 44+0 gestational weeks+days (whichever is sooner)
- 18. Receiving maternal breastmilk at discharge home or 44+0 gestational weeks+days (whichever is sooner)

neoGASTRIC SWAT secondary outcome is to evaluate the quality of parental decision making by using descriptive statistics.

Completion date

31/10/2026

Eligibility

Key inclusion criteria

Updated 08/01/2025: Corrected as of 03/04/2023:

- 1. Gestational age at birth less than 34+0 gestational weeks+days
- 2. Nasogastric or orogastric tube in place

Previous inclusion criteria:

- 1. Gestational age at birth less than 34+0 gestational weeks+days
- 2. Nasogastric or orogastric tube in place
- 3. Baby receiving less than or equal to 15 ml/kg/day of milk

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Αll

Key exclusion criteria

Updated 08/01/2025:

Current exclusion criteria as of 03/04/2023:

- 1. Infant has received more than 15ml/kg/day of milk for more than 24 hours
- 2. Gastrointestinal surgical condition (including suspected necrotising enterocolitis and focal intestinal perforation) prior to randomisation
- 3. Major congenital abnormalities
- 4. No realistic prospect of survival
- 5. A parent has opted out of infant's participation in neoGASTRIC

Previous exclusion criteria:

- 1. Infant has received more than 15ml/kg/day of milk for more than 24 hours
- 2. Gastrointestinal surgical condition prior to randomisation
- 3. Major congenital abnormalities

- 4. No realistic prospect of survival
- 5. A parent has opted out of infant's participation in neoGASTRIC

Original exclusion criteria:

- 1. Gastrointestinal surgical condition prior to randomisation
- 2. Major congenital abnormalities
- 3. No realistic prospect of survival
- 4. A parent has opted out of infant's participation in neoGASTRIC

Date of first enrolment

01/04/2023

Date of final enrolment

31/03/2026

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Australia

Study participating centre

Chelsea and Westminster Hospital NHS Foundation Trust

Chelsea & Westminster Hospital 369 Fulham Road London United Kingdom SW10 9NH

Study participating centre East Kent Hospitals University NHS Foundation Trust Kent & Canterbury Hospital

Ethelbert Road

Canterbury United Kingdom CT1 3NG

Study participating centre Belfast Health and Social Care Trust

Trust Headquarters A Floor - Belfast City Hospital Lisburn Road Belfast United Kingdom BT9 7AB

Study participating centre Bradford Teaching Hospitals NHS Foundation Trust

Bradford Royal Infirmary Duckworth Lane Bradford United Kingdom BD9 6RJ

Study participating centre Royal Cornwall Hospitals NHS Trust

Royal Cornwall Hospital Treliske Truro United Kingdom TR1 3LJ

Study participating centre University Hospitals of Derby and Burton NHS Foundation Trust

Royal Derby Hospital Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre Medway NHS Foundation Trust Medway Maritime Hospital

Windmill Road

Gillingham United Kingdom ME7 5NY

Study participating centre Hull University Teaching Hospitals NHS Trust

Hull Royal Infirmary Anlaby Road Hull United Kingdom HU3 2JZ

Study participating centre University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

Study participating centre Liverpool Women's NHS Foundation Trust

Liverpool Women's Hospital Crown Street Liverpool United Kingdom L8 7SS

Study participating centre Guy's and St Thomas' NHS Foundation Trust

Monkton Street London United Kingdom SE11 4TX

Study participating centre The Hillingdon Hospitals NHS Foundation Trust

Pield Heath Road Uxbridge United Kingdom UB8 3NN

Study participating centre Imperial College Healthcare NHS Trust

St Marys Hospital Praed Street London United Kingdom W2 1NY

Study participating centre Bedfordshire Hospitals NHS Foundation Trust

Lewsey Road Luton United Kingdom LU4 0DZ

Study participating centre Manchester University NHS Foundation Trust

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Study participating centre South Tees Hospitals NHS Foundation Trust

James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital Freeman Road High Heaton Newcastle upon Tyne United Kingdom NE7 7DN

Study participating centre Norfolk and Norwich University Hospitals NHS Foundation Trust

Colney Lane Colney Norwich United Kingdom NR4 7UY

Study participating centre Oxford University Hospitals NHS Foundation Trust

John Radcliffe Hospital Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre

Portsmouth Hospitals University National Health Service Trust

Queen Alexandra Hospital Southwick Hill Road Cosham Portsmouth United Kingdom PO6 3LY

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital Herries Road Sheffield United Kingdom S5 7AU

Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton General Hospital Tremona Road Southampton United Kingdom SO16 6YD

Study participating centre North Tees and Hartlepool NHS Foundation Trust

University Hospital of Hartlepool Holdforth Road Hartlepool United Kingdom TS24 9AH

Study participating centre Swansea Bay University Local Health Board

One Talbot Gateway, Seaway Drive Seaway Parade Industrial Estate Baglan Port Talbot United Kingdom SA12 7BR

Study participating centre Great Western Hospitals NHS Foundation Trust

Great Western Hospital Marlborough Road Swindon United Kingdom SN3 6BB

Study participating centre The Shrewsbury and Telford Hospital NHS Trust

Mytton Oak Road Shrewsbury United Kingdom SY3 8XQ

Study participating centre West Hertfordshire Teaching Hospitals NHS Trust

Trust Offices Watford General Hospital Vicarage Road Watford United Kingdom WD18 0HB

Study participating centre Monash Health

246 Clayton Road Clayton Victoria Clayton Australia 3168

Study participating centre The Royal Women's Hospital

20 Flemington Road Parkville Victoria Melbourne Australia 3052

Study participating centre Sydney Local Health District

Royal Prince Alfred Hospital
50 Missenden Road
Camperdown
NSW
Sydney
Australia
2050

Study participating centre Women's and Children's Health Network

The Women's and Children's Hospital
72 King William Road
North Adelaide
South Australia
North Adelaide
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5006

Study participating centre St George's University Hospitals NHS Foundation Trust St George's Hospital

Blackshaw Road Tooting London United Kingdom SW17 0QT

Study participating centre Betsi Cadwaladr University Lhb

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Study participating centre Hywel Dda Health Board

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Study participating centre Aneurin Bevan University Lhb

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Study participating centre University Hospitals Plymouth NHS Trust

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Study participating centre

Royal Devon University Healthcare NHS Foundation Trust

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Study participating centre North Bristol NHS Trust

Southmead Hospital Southmead Road Westbury-on-trym Bristol United Kingdom BS10 5NB

Study participating centre University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters Marlborough Street Bristol United Kingdom BS1 3NU

Study participating centre Torbay and South Devon NHS Foundation Trust

Torbay Hospital Newton Road Torquay United Kingdom TQ2 7AA

Study participating centre Wirral University Teaching Hospital NHS Foundation Trust

Arrowe Park Hospital Arrowe Park Road Upton Wirral United Kingdom CH49 5PE

Study participating centre Homerton Healthcare NHS Foundation Trust

Homerton Row London United Kingdom E9 6SR

Study participating centre North West Anglia NHS Foundation Trust

Peterborough City Hospital Bretton Gate Bretton Peterborough United Kingdom PE3 9GZ

Study participating centre Maidstone and Tunbridge Wells NHS Trust

The Maidstone Hospital Hermitage Lane Maidstone United Kingdom ME16 9QQ

Study participating centre Bolton NHS Foundation Trust

The Royal Bolton Hospital Minerva Road Farnworth Bolton United Kingdom BL4 0JR

Study participating centre Northern Lincolnshire and Goole NHS Foundation Trust

Diana Princess of Wales Hospital Scartho Road Grimsby United Kingdom DN33 2BA

Study participating centre London North West University Healthcare NHS Trust

Northwick Park Hospital Watford Road Harrow United Kingdom HA1 3UJ

Study participating centre Lancashire Teaching Hospitals NHS Foundation Trust

Royal Preston Hospital Sharoe Green Lane Fulwood Preston United Kingdom PR2 9HT

Study participating centre Whittington Health NHS Trust

The Whittington Hospital Magdala Avenue London United Kingdom N19 5NF

Sponsor information

Organisation

Imperial College London

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

National Health and Medical Research Council NIHR Collaborative Research Grant Scheme (NHMRC-NIHR)

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	02/12/2022	05/04/2023	No	No
Protocol file	version 3.0	19/04/2024	08/01/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes