

4. Randomisation

Prior to randomisation, please ensure:

- Eligibility has been confirmed by a delegated individual from the neoGASTRIC Site Delegation Log
- The parent has not opted-out of the study

Randomising infants to neoGASTRIC

The randomisation of infants is via a secure web-based randomisation tool hosted by the NPEU CTU Oxford with telephone backup available at all times.

Training on the randomisation process will be provided. This will consist of watching a short video to guide you through how to use the web-based randomisation tool.

Your site will be provided with a username and password.

! To note, if you experience any technical difficulties please see the technical support section at the end of this Guidance Sheet.

Quick guide to completing Randomisation

To randomise an infant, please follow the following steps:

1. Access the online randomisation website at:
<https://rct.npeu.ox.ac.uk/neogastric/>
 - a. Select your centre from the drop-down list
 - b. Enter your site username and password (located in your neoGASTRIC Document Box)
2. Once logged in, click “Enter baby”
 - a. Complete the questions related to eligibility of the infant. The person completing the form must be on the [Delegation Log](#) for randomisation.
 - b. Once the form has been completed, click “Continue”

! To note that any data that suggests the infant is ineligible will be flagged and you will not be able to proceed any further.

Section 1: Eligibility

Time of randomisation: 26 May 2023 13:58

Baby details

1.1 Baby's date and time of birth	24 / May / 2023 03 : 03 24hr clock
1.2 Baby's agreed gestation at birth	29 weeks + 0 days
1.3 Baby's weight at birth	1080 g
1.4 Is this baby one of a multiple pregnancy?	<input type="checkbox"/>
Inclusion criteria	
1.5 Does this baby have a nasogastric or orogastric tube in place?	<input type="checkbox"/>
Exclusion criteria	
1.6 Has this baby received more than 15 ml/kg/day of milk for more than 24 hours?	<input type="checkbox"/>
1.7 Prior to randomisation, was this baby diagnosed with a gastrointestinal surgical condition (including suspected necrotising enterocolitis or focal intestinal perforation)?	<input type="checkbox"/>

If unsure about the infants eligibility please discuss with the local PI before progressing with the randomisation.

- Please complete your name and email address
- Check that the data are correct. If any information is incorrect, click "Amend" and enter the corrected information before clicking "Complete"
- On the randomisation screen, the infant will be allocated a neoGASTRIC Study Number and allocated to either:

NO ROUTINE MEASUREMENT OF GASTRIC RESIDUAL VOLUMES

or

ROUTINE, UP TO 6 HOURLY, MEASUREMENT OF GASTRIC RESIDUAL VOLUMES

! To note that multiples will be randomised to the same arm.

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The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Each time a baby is randomised a notification email will be sent to the site staff that have been requested to receive this. If you want to add or remove anyone from this list, please email the neoGASTRIC team.

Contact Details Form

After randomisation, click the “Enter contact details” button. This will open up a new window to enter the contact details as required.

Technical Support

If you experience technical difficulties with internet access or the Randomisation website, or require technical support, please contact the neoGASTRIC study team using the contact details below:

- During office hours (Mon – Fri, 9am – 5pm), contact the neoGASTRIC study team on:
01865 617927 / neogastric@npeu.ox.ac.uk
- In the case of urgent out-of-hours queries, please see the [Emergency Queries Guidance Sheet](#).

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