neoGASTRIC

FAQS FOR SITES

ENROLMENT

1. **Who can assess for eligibility to the trial?**

   Appropriately trained and delegated clinicians, research nurses and health care professionals can carry out screening and eligibility checks.

2. **Could you clarify when you can randomise from a feed point of view?**

   Babies can be randomised until they have been receiving more than 15ml/kg/day for more than 24 hours. So in practice this means that babies can be randomised in the first 24 hours regardless of feed volume (as they will have received it for less than 24 hours), and those babies that have a period of 'trophic' feeds up to 15ml/kg/day can be randomised until they have had 24 hours on more than trophic feeds.

3. **Will staff who is randomising require GCP training?**

   No

4. **Is it a single site log in for randomisation?**

   There will be a site-wide log in for the randomisation system, which can be found on the lid of the document box provided to sites.

5. **On the day of randomisation, is the feeding log completed from the time of randomisation onwards?**

   On day 0, which is the day of randomisation, please can you complete the daily feed log for the whole 24 hour period, irrespective of the time of day the baby was randomised. Complete the feeding log for each calendar day (24 hours from 00:00).

6. **How "onerous" is the data collection? We don't all always have research nurses for example. Will the UK Badgenet platform help? Could Badgernet provide a prompt at admission for participating sites? Can the Leaflet be electronically given to the parents via Badgernet?**

   Only a small amount of trial data will need to be entered into the trial CRFs. We are exploring using the Badgernet system to help identify eligible babies and to link to the Parent Information Sheets (PIS). This answer will be updated as this develops.

7. **Can parents be approached before the screening log is completed? Can neoGASTRIC information be provided antenatally or when mum is on labour ward impending delivery?**

   Parents can absolutely be given information about the trial antenatally, but consent cannot be confirmed and the baby cannot be randomised until the baby is born.

8. **Is the Parent Information Sheet (PIS) available in other languages?**

   We have the PIS translated into 10 languages, including Welsh. If a language is not available, please use your usual translation systems in your hospital.

9. **As this is opt-out consent, do we go ahead once the Parent Information Sheet is handed to the parent? E.g. do we have to talk through the project with the parent as well? How does Opt-out consent work practically?**

   Once the parent has received the information sheet, and the parent has had some time to read this, the infant can be enrolled. You don't have to talk the study though with the parent, but please do if the parent has questions or needs anything clarified. The parent can opt-out at any time during the study if they decide later they don't want their child to take part. Please refer to Guidance Sheet 3 and contact the trial coordinating team at neogastric@npeu.ox.ac.uk if you have any further questions.

10. **How do we know that parents are reading the information we provide and will we be asking parents if they have read it?**

    The Research Ethics Committee (REC) that reviewed the study confirmed that they do not expect site staff to confirm with parents that they have read the information given. However you can chose to mark in their notes that the parent/carer has received the sheet.

    We advise that staff should give the study information to parents and maintain open communication. If the parents have questions, explain that this trial is exploring a practice that is variable throughout UK hospitals, and that there is no new treatment introduced. Instead of giving babies the current arbitrary care, this trial is formally randomising the different care pathways.

11. **Can participants be enrolled into neoGASTRIC and another study?**

    Infants enrolled in other interventional studies are eligible for participation in the neoGASTRIC trial, **including FEED1, DOLFIN and WHEAT trials**. However, please get in touch with neoGASTRIC study team if you have any further queries or concerns around this.

    FEED1:

    We have lots of discussion in both FEED1 and neoGASTRIC management and steering groups. As you have no doubt identified, one issue is that the FEED1 intervention (full feeds) will likely impact the outcome (time to reach full feeds) in neoGASTRIC. We are dealing with this by capturing details about whether babies recruited into neoGASTRIC are also enrolled in FEED1 and what FEED1 arm they are allocated to, so we can account for this in the neoGASTRIC analysis. There are likely to only be a small number of babies co-enrolled in FEED1 and neoGASTRIC (as FEED1 has a much narrower gestational window and is nearly finished; while neoGASTRIC is just starting), but we will monitor this.

12. **How palatable is co-enrolment for parents?**

    Parents often want to be in more than one trial if they feel like it is helpful and low risk. neoGASTRIC is exploring a practice that is variable throughout UK hospitals, and there is no new treatment introduced. Instead of giving babies the current arbitrary care, this trial is formally randomising the different care pathways. Please follow the links below for further information around the topic.

    Please find the link to the qualitative feasibility study paper for this trial, which highlights what parents prioritise when considering the trial and views on trial acceptability: https://pilotfeasibilitystudies.biomedcentral.com/articles/10.1186/s40814-021-00784-5

    Here is the full HTA report which includes views on approach to consent and outcomes: www.imperial.ac.uk/media/imperial-college/medicine/dept-medicine/infectious-diseases/neonatology/GASTRIC-Study-protocol-for-upload-HTA-V-2-9-March-2018.pdf

13. If there are safeguarding concerns around the baby, is it OK to enrol them?

This is a decision for the PI to make, but please do contact the neoGASTRIC team if you are not sure. If you think the parent/carer is not able to make an informed decision, please do not enrol them and mark this in the infants notes.

14. Can babies born to under 16 year old parents be included in the study?

If the parent/carer(s) is determined to be competent to understand the trial then the baby can be enrolled in the trial.