neoGASTRIC

FAQS FOR SITES

CLINICAL

1. **Define full feeds**

   Full feeds are defined as about 150ml/kg/day for 3 days (for the protocol this is ≥145ml/kg to allow rounding and small changes in a baby's weight).

2. **During our routine teaching with parents, we teach them how to perform a feed via an OGT/ NGT. We then sign parents' competencies. As part of the competencies, we advise parents to aspirate 0.5-1ml of gastric contents and check the PH using testing strips. Depending on the result we can then to proceed to feed. This is a safety element and forms a large part of their teaching and competencies. Will we be able to continue to do this to test the position of the tube if the baby is part of the trial?**

   Absolutely. It is an MHRA requirement to check NG or OG tube position and this is done by aspirating a ml or so of aspirate, and checking the pH (as described above). This is not affected by the trial and this must continue as normal. For babies allocated to the 'no routine measurement arm' however we would ask that you teach parents not to aspirate the entire stomach contents.

   The trial is only looking at the practice of aspirating the whole stomach contents routinely.

3. **The exclusion criteria is 'Gastrointestinal surgical condition (including suspected necrotising enterocolitis and focal intestinal perforation) prior to randomisation, but what if the baby has non-surgical related NEC?**

   It unlikely to be common for a baby to have NEC before randomisation in neoGASTRIC as randomisation needs to happen in the first few days after birth, but any suspected NEC at the time of randomisation would be an exclusion criterion.

4. **What do you mean by routine gastric residual volume at least 6 hourly? Does this mean 4 times a day? What are the guidelines?**

   Yes, at least four times a day, but you can measure gastric residuals more regularly than this, if that is your local policy. We also have a suggested approach that you may want to use for both trial arms, based on the survey of practice across the UK. Please see the protocol for more details.

5. **Can you return the aspirates back?**

   Yes, please follow your usual local procedure and return the gastric residual if this is what you would usually do.

6. **If an infant is in the no GRV measurement arm, and we need to aspirate for clinical reasons, is this a protocol deviation?**

   No, this is OK. Please detail this in the neoGASTRIC Daily Feed Log.

7. **What happens if a baby becomes "surgical" or develops NEC? Do they stay in the same arm or can you then measure residuals as clinically indicated?**

   Please measure GRV as clinically indicated. This situation is captured on the Daily Feed Log. When regular gastric residual measurement is no longer clinically indicated, the infant should be allocated back to their randomised care pathway if this is considered clinically appropriate.

8. **What happens when babies require aspiration of air from NG often for routine care e.g. very premature babies on non-invasive respiratory support?**

   Please measure GRV as clinically indicated. This situation is captured on the Daily Feed Log. When regular gastric residual measurement is no longer clinically indicated, the infant should be allocated back to their randomised care pathway if this is considered clinically appropriate.

9. **If baby is on the no GRV arm of the study but have had to have their NG tube aspirate, due to abdominal distention with large amounts of air aspirated. Their feeds were not stopped and they did not need to have any x-rays. Would you class this as a serious clinical concern for the study?**

   Abdominal distension due to air that is not accompanied by any other abdominal issues would not constitute a serious concern.

   It's perfectly OK for infants in either arm of the study to have air aspirated from the gastric tube, or for the tube to be left open to vent. We'd regard it as routine care and very common, especially for infants on CPAP. As long as aspiration is ceased when you stop getting air and start getting liquid, it fits within the protocol for the no aspirate arm.

   Feeding log (Day 1-14) and EBM (expressed breast milk):

10. **Were the baby's feeds withheld for any length of time on this day?**

    Essentially this question only applies if the feeds were intentionally withheld. If you have enrolled a baby but there is no milk that's different, so for this scenario I would mark that as no because they weren't intentionally withheld it's just that there was no milk available and that will be recorded in the total mls per day the baby received.

11. **Was the baby nil by mouth at any point today with the intention that this was 4 or more hours?**

    Again, if it's because there is no milk available then this would be marked as a no. It's only if there was intention that the baby was purposely made NBM because of gut related issues or potentially for a blood transfusion that we would log the period the baby was NBM for.