The GASTRIC-PICU Study

STUDY UPDATE MAY 2024

The study is progressing well - over 1,600 children have already been recruited. Thank you all for the hard work that has helped us achieve this! The study has an independent safety committee, and we can confirm that there have been **no concerns raised.**

Key points for bedside nurses:

- pH checks should be undertaken for all study patients (even those in the 'no GRV' group), to confirm the position of the gastric tube.
- pH checks must be clearly documented **as pH checks** (for both arms of the study)

'Usual care' patients

- GRV measurements must be clearly documented, even if the amount is zero. If a GRV measurement can't be done please document the reason why.
- GRV needs to be checked and measured in children with **gastrostomies**, even if this is not usual practice within your unit.

'No GRV' patients

- Please document pH checks clearly as '**pH check only**'. GRV should not be measured.
- Aspirating the stomach for clinical reasons is fine (e.g. vomiting, to remove air, bloating, etc.), but the reason must be documented.
- Not measuring GRV does not mean that you cannot remove air. If air builds up in the stomach and is not removed it may cause the child to vomit.

For all study patients

If the child has been randomised to the study and the parents were not at the bedside at the time, please can you speak to them when they visit. You can also point them towards the study video (which has optional translation into 26 different languages). We are also developing a leaflet for parents.

Key points for research delivery staff:

Consent:

- GASTRIC-PICU is approved to use 'research without prior consent' (RWPC) model because:
  a. most units start feeds early (within 6 hours). Waiting to get consent might delay the start of feeding.
  b. there are ethical concerns about the burden on parents/carers of trying to understand a study and provide informed consent during a period of acute illness.

The RWPC model, developed in line with the CONNECT study guidance, has been found to be acceptable to parents/carers and clinicians in several recent RCTs conducted in the PICU setting. **Findings from these studies have been incorporated into the GASTRIC-PICU consent procedure.**

- Allow time. This is a low-risk study. Research nurses should allow the parents adequate time, there is no urgency to get consent. Consent can be obtained even once the child has left PICU. Allowing the parents adequate time to consider the study without pressuring them is crucial.

Eligibility

- Children on long term NIV (who have required intubation) can be included in the study. It is only children on long-term invasive ventilation with a tracheostomy who cannot be included (because they will not reach the study endpoint of 'extubation'

Randomisation:

- the 'how to randomise a patient' guide is available for clinical staff. A 'trial summary for bedside teaching' is also available.

Contact us:
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