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Randomised Prospective Trial to compare the efficacy of bolus versus continuous nasogastric feeding in Paediatric Intensive Care

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/09/2015	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0220183296

Study information

Scientific Title
Randomised Prospective Trial to compare the efficacy of bolus versus continuous nasogastric feeding in Paediatric Intensive Care

Study objectives
The aim of the study is to compare bolus vs continuous nasogastric feeding in paediatric intensive care in achieving full nutritional requirement in the shortest time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective non-blinded randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Feeding in intensive care

Interventions
Informed written consent from the parent will be obtained by senior member of medical staff. All patients will be enrolled within 6 hours of admission to PIC. The duration of the study period will either be completion of 48 hours in either randomised arm or discharge from PIC if this occurs sooner. Patients will be randomised at enrolment. Randomisation envelopes will be held in the controlled drugs cabinet in the ICU.

Patients will be randomised to receive either Protocol A (bolus feeds) or Protocol B (continuous feeds). Protocol A and B will only commence after confirmation of nasogastric tube position as per Sheffield Children's Hospital guidelines (available on PIC). Patients' weight and total daily

fluid requirement noted (calculated on former as per PIC guidelines). All ventilated patients in PICU are fluid restricted to 80% of their total daily fluid requirement. The full feed allowance hence is 80% maintenance minus fluid administered as medications. Throughout the study period the nasogastric tubes will aspirated every 3 hours and the gastric residual volume recorded.

Intervention Type
Procedure/Surgery

Primary outcome measure
Time to achieve full entheral feeds by volume.

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/04/2006

Completion date
15/03/2007

Eligibility

Key inclusion criteria
As this study is to compare feeding tolerance in Paediatric Intensive Care, patients will be recruited from serial admissions to the PICU. This is a single centre study in a regional intensive care unit of a teaching hospital with 11 beds. All children aged 1 month to 16 years admitted during a period of 6 months. The study period may be shortened or lengthened depending on the sample size to justify enough power for statistical analysis, but it is anticipated that it will not exceed 12 months once started.

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
100

Key exclusion criteria

1. Children who have known gastro-oesophageal reflux disease, recent gastro-intestinal surgery, fundoplication, gastrostomy, inflammatory bowel disease, nasojejunal feeding, prokinetic use (Erythromycin, Clarithromycin or Domperidone) and any preset contra-indication to enteral feeds
2. Any patient requiring constant carbohydrate or dextrose input, eg metabolic patients
3. Patients participating in an ongoing research trial

Date of first enrolment
10/04/2006

Date of final enrolment
15/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Children's NHS Foundation Trust
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Sheffield Children's NHS Foundation Trust

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration