

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

Submission date

28/09/2007

Recruitment status

No longer recruiting

Registration date

28/09/2007

Overall study status

Completed

Last Edited

04/09/2015

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ 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

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

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

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