

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/09/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

Time to achieve full enteral feeds by volume.

### **Key secondary outcome(s)**

Not provided at time of registration

### **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

### Healthy volunteers allowed

No

### Age group

Child

### Lower age limit

1 months

### Upper age limit

16 years

### Sex

All

### 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

United Kingdom

England

**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

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Sheffield Children's NHS Foundation Trust

### **Funder Name**

NHS R&D Support Funding

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration