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The effect of early enteral feeding in patients suffering severe head injury and requiring mechanical ventilation

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
26/01/2010

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
R/TAYLOR/293

Study information

Scientific Title

Study objectives
Patients suffering severe head injury commonly receive inadequate nutritional support for >5 days. Recent evidence suggests this is associated with an increased mortality and poor long-term outcome. However, the studies done so far have used early parenteral feeding to improve outcome. Parenteral feeding is itself a relatively high risk and high cost procedure. We propose to test the efficacy of early jejunal enteral feeding versus standard gastric enteral feeding in a prospective randomised controlled trial in patients with severe head injury, requiring mechanical ventilation. Retrospective analysis would specifically control for disease severity (Glasgow Coma Scale and Acute Physiology And Chronic Health Evaluation [APACHE] II) as well as other demographic and clinical parameters measured during the study. The aim is to determine the degree of clinical and functional benefit accruing from early enteral feeding (if any) and to differentiate possible sub-populations that most benefit from such treatment. Lastly, from metabolic data we hope to be able to postulate mechanisms for the effect of nutritional support and thus guide future research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Brain injury

Interventions
1. Early jejunal enteral feeding
2. Standard gastric enteral feeding

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neurological outcome (Glasgow Outcome Scale 4 or 5) was determined at 3 and 6 months post injury and the incidence of infective and total complications was determined for hospital admission.

Secondary outcome measures
Not provided at time of registration

Overall study start date
20/06/1994

Completion date
31/10/1997

Eligibility

Key inclusion criteria
Patients with severe head injury requiring mechanical ventilation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
82 (added 26/01/10; see publication)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
20/06/1994

Date of final enrolment
31/10/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS16 9DA

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
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SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/1999		Yes	No