

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

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

26/01/2010

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Stephen Taylor

Contact details

North Bristol NHS Trust

7 Balmoral Court

Mangotsfield

Bristol

United Kingdom

BS16 9DA

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/1997

Eligibility

Key inclusion criteria

Patients with severe head injury requiring mechanical ventilation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

North Bristol NHS Trust

Bristol

United Kingdom

BS16 9DA

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (UK)

Results and Publications

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