

A prospective, pilot, randomised, controlled trial of continuous versus bolus feeding in gastrostomy fed patients

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/03/2018	Condition category Surgery	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0192147123

Study information

Scientific Title

A prospective, pilot, randomised, controlled trial of continuous versus bolus feeding in gastrostomy fed patients

Study objectives

To establish in patients being fed by Percutaneous Endoscopic Gastrostomy (PEG) whether bolus fed patients have a lower incidence of feeding related complications than patients fed via continuous infusion and to determine patient preference between the two methods of feeding.

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)

Other

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Gastrostomy

Interventions

Randomised Controlled Trial:

1: Continuous Feeding

2: Bolus Feeding

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

To examine the differences in enteral feeding complication in those patients who are fed via continuous infusion or via bolus feeding.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2004

Completion date

30/09/2005

Eligibility

Key inclusion criteria

60 patients being fed Percutaneous Endoscopic Gastrostomy (PEG).
Patient and/or carer must, in the opinion of the researcher be able to comply with the protocol.
Anticipated length of time on tube feeding greater than the study period: 10 weeks. Patient suitable for standard polymeric fibre feed: patients not taking diet orally.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

60

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2004

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Consultant in Gastroenterology and Clinical Nutrition
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust (UK)

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