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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	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/03/2018	**Condition category** Surgery	[_] 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

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
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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