A comparison of endoscopic and radiological methods of placement of large bore gastrostomy tubes

Submission date	Recruitment status	Prospectively registered
12/09/2003	Stopped	Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Stopped	Results
Last Edited	Condition category	Individual participant data
11/02/2010	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0226118476

Study information

Scientific Title

Study objectives

To compare the success and complication rates of the modified and the endoscopic method in a prospective randomised study.

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

Gastrostomy tube insertion

Interventions

To compare the success and complication rates of the modified and the endoscopic method.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Successful insertion of gastrostomy tube at the first attempt.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2002

Completion date

01/12/2004

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

200 Consecutive patients undergoing percutaneous gastrostomy (100 each arm).

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

200

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/2002

Date of final enrolment

01/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Main X Ray Area A

Manchester

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

South Manchester University Hospitals NHS Trust (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