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

Submission date 12/09/2003	Recruitment status Stopped	 Prospectively re Protocol
Registration date 12/09/2003	Overall study status Stopped	 Statistical analys Results
Last Edited 11/02/2010	Condition category Surgery	 Individual partic Record updated

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

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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 United Kingdom M23 9LT

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