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Laparoscopic gastrojejunostomy versus self expanding metal stent for malignant gastric outlet obstruction: a prospective randomised trial

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 17/07/2008	**Condition category** Surgery	

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
N0547102224

Study information

Scientific Title

Study objectives
1. To investigate whether self expanding metal stents are comparable to laparoscopic gastrojejunostomy in treating malignant gastric outlet obstruction
2. To evaluate the cost effectiveness of both treatments
3. To examine the effects of both treatments on quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Gastrojejunostomy

Interventions
Laparoscopic gastrojejunostomy versus self expanding metal stent for malignant gastric outlet obstruction

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/07/2001

Completion date
10/07/2004

Eligibility

Key inclusion criteria
20 per year

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 anticipated. Added July 2008: 27 patients enrolled.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
10/07/2001

Date of final enrolment
10/07/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Consultant Surgeon
Norwich
United Kingdom
NR1 3SR

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
Government

Funder Name
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital /Norwich PCT (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2006		Yes	No