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Multi centre randomised prospective trial of duodenal stenting versus surgical gastrojejunostomy for palliative relief of gastric outlet obstruction secondary to inoperable peri-ampullary cancers

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 23/05/2012	**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
N0256107988

Study information

Scientific Title

Study objectives
Which method of gastric bypass offers the best palliation with lowest cost and least mortality and morbidity?

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)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Gastric bypass

Interventions
Patients randomised to receive duodenal stenting or surgical bypass. Followed up until death with analysis of morbidity, mortality, survival, cost, readmission rates, palliation of symptoms and quality of life.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
30 Day mortality, morbidity, cost, quality of life, survival after treatment, recurrent hospital admissions and reasons, successful placement of stents, return to nutrition and level of return to nutrition.

Secondary outcome measures
Not provided at time of registration

Overall study start date
03/01/2002

Completion date
03/01/2004

Eligibility

Key inclusion criteria
35 patients in each group.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
70

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
03/01/2002

Date of final enrolment
03/01/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Department of Surgery
London
United Kingdom
NW3 2QG

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
The Royal Free Hampstead 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2007		Yes	No