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

Submission date 12/09/2003	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 12/09/2003	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 23/05/2012	Condition category Surgery	[_] Individual participant data

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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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?
<u>Results article</u>	results	01/06/2007		Yes	No