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Intra-operative balloon dilatation of the pylorus in oesophagogastrectomy

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 16/03/2016	**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
N0051127200

Study information

Scientific Title
Intra-operative balloon dilatation of the pylorus in oesophagogastrectomy

Study objectives
To determine if routine intra-operative balloon dilatation of the pylorus eliminates delayed gastric emptying and may therefore be a feasible alternative to pyloroplasty/pyloromyotomy.

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

Health condition(s) or problem(s) studied
Oesophagogastrectomy

Interventions
Randomised Controlled Trial to determine if routine intra-operative balloon dilatation of the pylorus eliminates delayed gastric emptying and may therefore be a feasible alternative to pyloroplasty/pyloromyotomy.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Contrast swallow score
2. Symptom score
3. Weight gain

4. Duodenogastric reflux
5. Oesophageal acid reflux

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2003

Completion date
31/03/2005

Eligibility

Key inclusion criteria
Patients undergoing oesophagogastrectomy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/04/2003

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (RSCH)
Brighton

United Kingdom
BN2 5BE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Brighton and Sussex 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