

Intra-operative balloon dilatation of the pylorus in oesophagogastrectomy

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oesophagogastrrectomy

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(s)

1. Contrast swallow score
2. Symptom score
3. Weight gain
4. Duodenogastric reflux
5. Oesophageal acid reflux

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/03/2005

Eligibility**Key inclusion criteria**

Patients undergoing oesophagogastrrectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Brighton & Sussex University Hospitals NHS Trust (RSCH)

Brighton

United Kingdom

BN2 5BE

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Brighton and Sussex University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration