# Intra-operative balloon dilatation of the pylorus in oesophagogastrectomy

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

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

Dr Donald Manifold

#### Contact details

Brighton & Sussex University Hospitals NHS Trust (RSCH)
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE
+44 (0)1273 696955
donald.manifold@bsuh.nhs.uk

### 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

### 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