ISRCTN05817794 https://doi.org/10.1186/ISRCTN05817794

Stenting in benign oesophageal stricture

Submission date 28/07/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/08/2010	**Overall study status** Completed	
Last Edited 05/02/2016	**Condition category** Digestive System	

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
PB-PG-1208-17025

Study information

Scientific Title
Biodegradable stent in benign oesophageal stricture compared to standard balloon dilatation treatment: a two-arm 1:1 randomised clinical trial

Acronym
BESST

Study objectives
This pilot study addresses the potential effectiveness and cost-effectiveness of biodegradable stent placement in patients with benign oesophageal stricture. The study will determine the feasibility and utility of a randomised controlled trial design comparing biodegradable oesophageal stent or standard dilatation in symptomatic adult patients diagnosed with refractory oesophageal stricture.

The primary endpoint will be ability to swallow, assessed by a five point dysphagia score (assessed by a blinded observer at baseline, 3, 6 and 12 months). Secondary end points will include the acceptability of procedures and overall care to patients, the number of repeat endoscopic procedures (therapeutic and diagnostic), adverse events (including hospital admissions), quality of life assessed physically using surrogate markers such as weight and serum albumin and by generic quality of life assessment (EuroQol EQ-5D) and economic analysis.

Economic analysis will be conducted from an NHS perspective. Stochastic cost-effectiveness analysis will use patient-level, within-trial (1 year) cost and quality-adjusted life-year (QALY) data. Modelling using probabilistic methods will explore extrapolations of benefits beyond one-year.

The summative aim is to show the potential value of a new treatment option which may improve the quality of life for patients and be a cost-effective alternative for the NHS. The proposed pilot study is an essential step to establish the need for a larger trial and to provide the necessary evidence base to inform patients and the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Two-arm 1:1 prospective randomised controlled clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Benign oesophageal strictures

Interventions
The study will involve endoscopic interventions of balloon dilatation with or without fluroscopy in one (control) arm and placement of a biodegradable stent in the other arm.

The treatment in each arm is a one time procedure. Patients will be followed up for a period of 12 months after the endoscopic intervention in each arm.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The average dysphagia (swallowing) score response over 12 months

Key secondary outcome(s)
1. Acceptibility of procedures to patients
2. Number of repeat endoscopic procedures
3. Frequency of refractory disease
4. Adverse events
5. Quality of life assessed physically using surrogate markers of weight, serum albumin and by generic quality of life assessment (EuroQol EQ-5D)
6. Patient level, NHS perspective, cost and cost-effectiveness analysis

Measured at 3, 6 and 12 months following the endoscopic intervention in both arms

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Signed written informed consent
2. Confirmed diagnosis of benign oesophageal stricture
3. Adults aged between 18 and 75 years, either sex
4. At least one previous oesophageal dilatation for management of their benign oesophageal stricture

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria

1. Patients who do not fulfil the inclusion criteria
2. Patients with high strictures
3. Pregnant patients
4. Receiving anti-coagulants
5. Diagnosis or oesophageal cancer
6. Diagnosis of a terminal disease
7. A history of any medical illness which, in the Investigator's discretion would inhibit the patient's participation
8. Women of child bearing potential who refuse to use adequate contraception for three months post-intervention

Date of first enrolment
01/11/2010

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Darlington Memorial and Bishop Auckland Hospitals
Department of Gastroenterology
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DL14 6AD

Sponsor information

Organisation
County Durham and Darlington NHS Foundation Trust (UK)

ROR
https://ror.org/03vamsh08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-1208-17025)

Results and Publications

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	28/12/2014		Yes	No