ISRCTN70483153 https://doi.org/10.1186/ISRCTN70483153

# The BioStent study: Biodegradable oesophageal Stents plus radiotherapy in carcinoma of the oesophagus

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| **Submission date**<br>22/05/2014 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>22/05/2014 | **Overall study status**<br>Completed | |
| **Last Edited**<br>15/11/2022 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-biodegradable-stents-and-radiotherapy-for-cancer-of-the-oesophagus-biostent

## Contact information

**Type(s)**
Scientific

**Contact name**
Ms Kelly Cozens

**Contact details**
MP131 University of Southampton Clinical Trials Unit
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)23 8120 8834
K.Cozens@southampton.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

16452

# Study information

### Scientific Title
The BioStent study: Biodegradable oesophageal Stents plus radiotherapy in carcinoma of the oesophagus: a non-randomised trial

### Acronym
BioStent

### Study objectives
To determine whether, for this patient group, a treatment comprising biodegradable (BD) stent plus 1-2 weeks of radiotherapy (RT) is sufficiently effective in palliating dysphagia in terms of re-intervention rates to warrant a randomised controlled trial (RCT) against the current standard of care, at present self-expanding metal stent (SEMS).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee London – Dulwich, 12/06/2014, ref: 14/LO/0389 (ammendment received 29/10 /2015)

### Study design
Non-randomised; Interventional and Observational; Design type: Treatment, Qualitative

### Primary study design
Interventional

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Upper Gastro-Intestinal Cancer; Disease: Oesophagus

### Interventions
Biodegradable Stent: Biodegradable (BD) stents manufactured by Ella-CS, Hradec Kralove, Czech Republic will be inserted in accordance with the standard procedures of the treating centre. Radiotherapy: Radiotherapy dose will be prescribed to the midplane and will be 20Gy in 5 daily fractions over one week or 30Gy in 10 daily fractions over two weeks.; Follow Up Length: 12 month(s); Study Entry : Registration only

### Intervention Type
Other

### Phase
Phase II

### Primary outcome measure
Need for a further intervention for dysphagia; Timepoint(s): 16 weeks following stent insertion.

### Secondary outcome measures
1. Description of changes in overall symptom/quality of life/anxiety & depression/nutrition scores; Timepoint(s): 52 weeks from Stent insertion
2. Feasibility of collecting overall symptom/QoL/anxiety&depression scores in this patient group; Timepoint(s): 52 weeks from Stent Insertion
3. Median times to deterioration of these scores.; Timepoint(s): 52 weeks from Stent insertion
4. Overall survival; Timepoint(s): 52 weeks from Stent insertion
5. Patient and carer experience of trial processes, intervention-related support needs, & effect of; Timepoint(s): intervention on daily living (qualitative sub-study). 52 weeks from Stent insertion
6. The incidence and severity of stent related side effects/complications; Timepoint(s): 52 weeks from Stent insertion

### Overall study start date
01/07/2014

### Completion date
01/07/2018

## Eligibility

### Key inclusion criteria
Eligible patients are those who would currently be offered a metal stent to palliate the symptom of dysphagia associated with their incurable oesophageal cancer and who are suitable for radiotherapy.
Specific eligibility criteria are:
1. Histologically confirmed primary adenocarcinoma or squamous cell carcinoma of the oesophagus.
2. Patients with poorly differentiated carcinoma thought to be of adenocarcinoma or squamous origin.
3. Not suitable for radical surgery, radical radiotherapy, or concurrent chemoradiotherapy as a result of disease extent, comorbidities, performance status or patient choice.
4. Oesophageal stent indicated and thought feasible.
5. Estimated life expectancy thought to be 16 weeks or more (amended from 12 weeks as of 14 /04/2016)
6 Thought willing and able to comply with study interventions and assessments.
7. Aged 18 years or more.
8. Able to give informed consent.
9. If subsequent chemotherapy is planned it is suggested that there is a minimum 2 week gap between the final fraction of radiotherapy and the first dose of chemotherapy.

Patients will be invited to nominate the person, friend or relative, who is mostly responsible for providing unpaid care at home ('caregiver'). This person must be:
1. Over 18 years
2. Able to give informed consent
3. Nominated by the patient

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 59; UK Sample Size: 59

### Total final enrolment
14

### Key exclusion criteria
1. Prior radical surgery for oesophagus cancer.
2. Chemotherapy in the 4 weeks prior to the start of radiotherapy.
3. Prior radiotherapy to the region of the tumour.
4. Known contraindication to radiotherapy.
5. Patients with small cell carcinoma, other neuroendocrine tumours or other histologies.
6. Presence of tracheooesophageal fistula.
7. Oesophageal tumour length more than 12cm.
8. Tumour within 2cm of the upper oesophageal sphincter.
9. Pregnancy.
10. Existing enteral tube feeding (unless removal planned prior to trial entry).
11. Clinical significant GI bleed eg. Hematemesis, Melena or coffee ground hematemesis within the last 6 months. (added 14/04/2016)

### Date of first enrolment
01/07/2014

### Date of final enrolment
02/04/2017

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University Hospital Southampton**
Tremona Rd
Southampton
United Kingdom
SO16 6YD

### Study participating centre
**Basingstoke and North Hampshire Hospital**
Aldermaston Rd
Basingstoke
Hampshire
United Kingdom
RG24 9NA

### Study participating centre
**Christie NHS Foundation Trust**
550 Wilmslow Rd
Manchester
United Kingdom
M20 4BX

## Sponsor information

### Organisation
Southampton University Hospitals NHS Trust (UK)

### Sponsor details
Cancer Care Directorate
B Level, Mailpoint WRE
Royal South Hants Hospital, Graham Road
Southampton
England
United Kingdom
SO14 0YG

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/0485axj58

# Funder(s)

### Funder type
Government

### Funder Name
NIHR Research for Patient Benefit (RfPB)

# Results and Publications

### Publication and dissemination plan
At trial closure and following consent from the TMG and DMEC the results will be published in peer review journals, conference presentations and dissemination at local and national oesophageal cancer patient groups.

### Intention to publish date
01/07/2018

### Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/05/2021 | 07/05/2021 | Yes | No |
| Plain English results | | | 15/11/2022 | No | Yes |
| HRA research summary | | | 28/06/2023 | No | No |