

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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>22/05/2014   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>22/05/2014 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>15/11/2022       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

## 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

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### Contact details

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## Additional identifiers

### Protocol serial number

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 (amendment received 29/10/2015)

## **Study design**

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

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**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 tracheoesophageal 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**

United Kingdom

England

**Study participating centre**

**University Hospital Southampton**

Tremona Rd

Southampton

United Kingdom

SO16 6YD

**Study participating centre**

**Basingstoke and North Hampshire Hospital**

Aldermaston Rd

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

## Sponsor information

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

**ROR**  
<https://ror.org/0485axj58>

## Funder(s)

**Funder type**  
Government

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

## Results and Publications

### 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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      |         | 01/05/2021   | 07/05/2021 | Yes            | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |

[Plain English results](#)

15/11/2022

No

Yes