

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

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

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 (ammendment 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 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

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

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)

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?
Results article		01/05/2021	07/05/2021	Yes	No
HRA research summary			28/06/2023	No	No

[Plain English results](#)

15/11/2022

No

Yes