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

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

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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
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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