ISRCTN54190466 https://doi.org/10.1186/ISRCTN54190466

Randomised controlled trial of surveillance and no surveillance for patients with Barrett's oesophagus

Submission date 27/12/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/01/2008	**Overall study status** Completed	
Last Edited 01/07/2022	**Condition category** Digestive System	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-how-often-to-monitor-people-with-barretts-oesophagus

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00987857

Secondary identifying numbers
HTA 05/12/01

Study information

Scientific Title
Randomised controlled trial of surveillance and no surveillance for patients with Barrett's oesophagus: BOSS (Barrett's Oesophagus Surveillance Study)

Acronym
BOSS

Study objectives
Comparison of endoscopic surveillance verus no endoscopic surveillance for the prevention of early mortality and the development of oesophageal adenocarcinoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submission pending as of 02/01/2008

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Barrett's oesophagus

Interventions
Upper gastrointestinalendoscopy every 2 years for 10 years

Intervention Type
Procedure/Surgery

Primary outcome measure
1. All causes mortality
2. Death from adenocarcinoma
3. Development of treatable adenocarcinoma
Duration of follow-up: 10 years

Secondary outcome measures
1. Quality of life: Reflux Questionnaire and EQ50 Quality of Life Questionnaire at yearly intervals by post
2. Cost effectiveness of endoscopy

Overall study start date
01/09/2009

Completion date
30/06/2022

Eligibility

Key inclusion criteria
Patients over 18 with endoscopic and histologically proven barrett's oesophagus greater than 1 cm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2,500

Total final enrolment
3520

Key exclusion criteria
1. Unable to give consent
2. Unable to tolerate upper gastrointestinal endoscopy

Date of first enrolment
01/09/2009

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gloucestershire Royal Hospital
Gloucester
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GL1 3NN

Sponsor information

Organisation
Gloucestershire Royal NHS Foundation Trust (UK)

Sponsor details
Research and Development Support Unit
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04mw34986

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/09/2015		Yes	No