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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

ClinicalTrials.gov (NCT)
NCT00987857

Protocol serial number
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

Study type(s)
Screening

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(s)
1. All causes mortality
2. Death from adenocarcinoma
3. Development of treatable adenocarcinoma
Duration of follow-up: 10 years

Key secondary outcome(s))
1. Quality of life: Reflux Questionnaire and EQ50 Quality of Life Questionnaire at yearly intervals by post
2. Cost effectiveness of endoscopy

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Gloucestershire Royal Hospital
Gloucester
United Kingdom
GL1 3NN

Sponsor information

Organisation
Gloucestershire Royal NHS Foundation Trust (UK)

ROR
https://ror.org/04mw34986

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/09/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes