

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

Submission date 27/12/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/07/2022	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

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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 versus 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 gastrointestinal endoscopy 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