

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

<b>Submission date</b> 27/12/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/07/2022	<b>Condition category</b> 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

Prof Hugh Barr

### Contact details

Gloucestershire Royal Hospital  
Great Western Road  
Gloucester  
United Kingdom  
GL1 3NN

-

[hugh.barr@nhs.net](mailto:hugh.barr@nhs.net)

## 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 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

## 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 gastrointestinal endoscopy 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

United Kingdom

GL1 3NN

# Sponsor information

## Organisation

Gloucestershire Royal NHS Foundation Trust (UK)

## Sponsor details

Research and Development Support Unit

Great western Road

Gloucester

England

United Kingdom

GL1 3NN

+44 (0)8454 226679

[hugh.barr@glos.nhs.uk](mailto:hugh.barr@glos.nhs.uk)

## 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?
<a href="#">Protocol article</a>	protocol	01/09/2015		Yes	No