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

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

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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	5 No	Yes