

## PATIENT SUMMARY SHEET

This is a trial funded by the **National Institute for Health Research** through the **NIHR Health Technology Assessment Programme**, and run by the Research and Development Support Unit based at Gloucestershire Hospitals NHS Foundation Trust. We are looking for patients from many areas of the UK.

The aim of the study is to see whether regular endoscopic surveillance is better than endoscopy at need for detecting any early signs of oesophageal cancer in patients diagnosed with Barrett's oesophagus.

Guidelines have been developed to check for early development of cancer using endoscopy. However these guidelines acknowledge that there is low confidence in the information available to support endoscopic surveillance in patients with Barrett's oesophagus, and the value of surveillance is still subject to considerable debate. The most appropriate method of evaluating whether surveillance is appropriate is through a randomised controlled trial.

The study randomises patients to receive a standard upper gastrointestinal endoscopy with biopsy every two years for 10 years or endoscopy at need. **Those patients randomised to endoscopy at need will be free to request an endoscopy at any time if they have concerns.** (This would also apply to those allocated 2 yearly endoscopy). All patients will receive a questionnaire every 2 years or after each endoscopy (which ever is sooner, to record their symptoms) and other health related data. (Those patients randomised to endoscopy at need will be sent theirs by the trial centre).

### Rationale for the study

Barrett's oesophagus is a change in the lower gullet (oesophagus) brought about by the frequent reflux of gastric juice from the stomach into the oesophagus. The lining of the lower oesophagus changes to become like the lining of the small intestine. Barrett's oesophagus affects approximately 1% of the population.

A small number of patients with Barrett's oesophagus may go on to develop oesophageal cancer.

We are conducting the BOSS study because we are not sure whether regular endoscopy, is beneficial to patients with Barrett's oesophagus or whether using patients' symptoms could be just as good. It should be important to find out if regular endoscopy benefits patients before routinely offering it.

### How many patients will be involved?

A total of 2,500 Barrett's patients (1,250 in each group) will be invited to join this trial over the next 2 years. You will then be followed up for a further 10 years.

### How to register interest:

If you have Barrett's oesophagus and would like to take part in this trial please ask your hospital doctor / research nurse for further details. They will be happy to give you the full patient information sheet.

Alternatively please contact:  
The BOSS Trial Team at Leadon House  
Gloucestershire Royal Hospital  
Great Western Road  
Gloucester GL1 3NN  
Telephone: 08454 225465

### Taking part in this trial is purely voluntary