ISRCTN58235785 https://doi.org/10.1186/ISRCTN58235785

Barrett's oesophagus surveillance with optical biopsy using spectroscopy and enhanced endoscopic imaging to target high-risk lesions

Submission date
31/08/2016

Recruitment status
No longer recruiting

Registration date
30/09/2016

Overall study status
Completed

Last Edited
25/07/2017

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An endoscopy is a procedure where the inside of the body is examined using an endoscope - a long, thin, flexible tube that has a light source and a video camera at one end. Small samples of tissue (biopsies) are also taken from the lining of the gut. A large number of biopsies are sometimes taken, particularly if a problem is suspected which cannot be seen, such as Barrett's oesophagus, a condition where the cells of the oesophagus (gullet) grow abnormally which can develop into cancer. Specimens are sent to the laboratory for the pathologists to analyse, and it can take up to 3 weeks to get the result. Devices are being researched that can be used to accurately detect abnormalities within the gut without having to take biopsies. An accurate and effective device would bring huge benefits to patients and the NHS. The aim of this study is to find whether optical biopsy is a quicker and less invasive way to identify abnormalities in the gut.

Who can participate?
Patients undergoing endoscopy who do or do not have Barrett's oesophagus

What does the study involve?
Participants come to the endoscopy unit for the camera test and for biopsies as per normal. Before the procedure they may be asked to give a blood and saliva sample as well as a painless swab taken from the inside of their cheek. During the endoscopy, before the tissue samples are taken, an optical fibre may be placed down the endoscope and a short burst of normal (white) light is passed down the fibre. The light that is reflected back up the fibre is analysed by a computer to obtain diagnostic information (optical biopsy). Routine tissue samples are then taken from the same area. A tissue sample from a nearby area of normal tissue is also taken in order to compare the results from normal and abnormal tissue. Up to four extra tissue samples, up to two cell samples, and a sample of fluid from the gut may also be sent to the pathology laboratory for analysis. The tissue sample results are then compared with the results of the optical biopsies.

What are the possible benefits and risks of participating?
This study may not directly help the participants, but may help patients in the future by giving an

immediate result, both reducing the number of biopsies taken and the waiting time for results. There is no extra risk involved apart from prolonging the endoscopic examination by a few minutes and taking the extra tissue samples, although this is extremely safe. The light measurement only takes a few seconds and the power of light used is so low that it doesn't affect the participant in any way. The optical biopsy only increases the time of the endoscopy procedure by a few minutes and does not cause any additional discomfort. The taking of tissue samples, brushings and fluid is painless, safe and again only adds minutes to the procedure.

Where is the study run from?
University College London Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2008 to March 2017

Who is funding the study?
University College London (UK)

Who is the main contact?
Dr Sarah Jevons

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Jevons

Contact details
University College London
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Additional identifiers

Protocol serial number
Version 8

Study information

Scientific Title
Barrett's oesophagus surveillance with optical biopsy using spectroscopy and enhanced endoscopic imaging to target high-risk lesions: a prospective cohort study

Acronym
BOOST

Study objectives

The trialists are researching devices that can be used to accurately detect abnormalities within the gut without having to take samples (biopsy). At present the devices being tested are elastic scattering spectroscopy (ESS), Fourier transform mid-infrared spectroscopy (FTIRS) and enhanced endoscopic imaging as well as changes to the composition of blood and saliva that would suggest an abnormality within the gut. The aim is to identify if any of the devices being tested might be able tell us immediately if an abnormality is present without having to examine a tissue sample under a microscope.

Medical device evaluation in prospective cohort study:
1. To determine whether optical biopsy can accurately predict cancer risk during surveillance endoscopy in patients without the need for further biopsies at all, particularly in patients undergoing routine endoscopic surveillance who are at low risk of progressing to oesophageal cancer.
2. To determine whether optical biopsy and other optical and biomarker techniques can be used to target biopsies to areas of dysplasia, aneuploidy or other molecular abnormalities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Dulwich Research Ethics Committee, 01/12/2015, ref: 08/H0808/8

Primary study design
Observational

Study design
Prospective cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Barrett's oesophagus, dysplasia, aneuploidy or other molecular abnormalities and oesophageal adenocarcinoma

Interventions
A series of optical measurements are taken followed by routine biopsies, some of which may be initially examined ex vivo using ESS and/or FTIRS before being sent for histological evaluation. Correlation is made between the optical measurements (both in and ex vivo) and the histological diagnosis. Up to four extra biopsies, two cytology brush samples and oesophageal/stomach /small bowel fluid samples may also be taken, as well as saliva to store for later analysis of other molecular markers and to correlate these with optical measurements. These ‘optical biopsy’ measurements and extra biopsies are taken from patients with no obvious oesophageal disease and from patients with cancer as controls to compare with patients with Barrett's.

Intervention Type
Device

Primary outcome(s)
1. Predictive accuracy of in vivo ESS for future cancer risk, particularly in patients undergoing routine endoscopic surveillance who are at low risk of progressing to oesophageal cancer

2. Ability to correlate endoscopy findings with cancer risk using genetic analysis of tissue or fluid samples
3. Predictive accuracy of ex vivo ESS and/or FTIRS for future cancer risk, particularly in patients undergoing routine endoscopic surveillance who are at low risk of progressing to oesophageal cancer
4. Ability of in vivo ESS to target biopsies to areas of dysplasia, aneuploidy or other molecular abnormalities

Key secondary outcome(s)
Ability of enhanced endoscopic imaging techniques including iScan to improve dysplasia detection and minimize the need for biopsies during endoscopic surveillance procedures

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Patients will be recruited from those with Barrett's oesophagus with or without other alterations (low-grade dysplasia [LGD] or high-grade dysplasia [HGD], any oesophageal or gastric cancer) undergoing endoscopy
2. Patients without Barrett's oesophagus attending for a clinically indicated endoscopy may be recruited as controls
3. Patients must sign an informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients in whom endoscopy and biopsy is contraindicated
2. Patients who are unable to give informed consent
3. Pregnant women
4. People under the age of 21 years
5. People who are non-English speakers

Date of first enrolment
05/06/2008

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
235 Euston Road
Fitzrovia
London
United Kingdom
NW1 2BU

Study participating centre
Nottingham University Hospitals NHS Foundation Trust
Hucknall Road
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NG5 1PB

Sponsor information

Organisation
UCL Biomedical Research Unit

Organisation
University College London Hospital

Organisation
UCL Biomedical Research Centre

ROR
https://ror.org/03r9qc142

Funder(s)

Funder type
University/education

Funder Name
University College London

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2017		Yes	No