The E.G. Study

| Submission date | Recruitment status No longer recruiting | Prospectively registeredProtocol | | |
|-------------------|---|---|--|--|
| 16/08/2012 | | | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 16/08/2012 | Completed | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 07/08/2018 | Digestive System | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Samantha Warburton

Contact details

Nottingham University Hospitals NHS Trust Biomedical Research Centre Queens Medical Centre Derby Road Nottingham United Kingdom NG7 2UH +44 115 924 9924 ext. 70612 samantha.warburton@nuh.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT02066233

Protocol serial number

12466

Study information

Scientific Title

A multi-centre observational study to assess a novel endoscopic device in imaging the upper gastrointestinal (GI) tract: The E.G. Scan Study

Study objectives

There are certain silent conditions like Barretts Oesophagus (a condition which can rarely cause cancer of the gullet) and Oesophageal Varices (swollen veins in the gullet which can sometimes cause serious bleeding) that can happen in patients who may otherwise not have any symptoms. If these are detected and treated early then patients could potentially avoid future serious complications. In order to detect these conditions, doctors have to perform tests on a large number of patients who are likely to have them, but unfortunately this cannot be done in the NHS at the moment partly because there is no agreement among specialists as to what is the best test to use.

Although a standard camera test can detect these conditions, it is not suitable to use for this purpose because it has many limitations. It is performed in the hospital usually under conscious sedation to increase comfort. Performing the test demands a lot of planning and has many cost considerations as it requires patient observation, experienced nursing staff, recovery rooms, cleaning equipment and medications.

There is a lot of research evidence that transnasal cameras (very thin cameras inserted through the nose) are more comfortable to patients because they do not cause gagging and retching, therefore do not require sedation. They are safer than standard cameras and are as accurate.

The purpose of this study is to compare a new camera called The E.G. scan to the standard camera test. We want to know whether it is as accurate and also whether it is acceptable to patients. It is much thinner than the standard camera test, therefore can be inserted through the nose with less chance of retching and gagging. It does not need sedation. The camera tube is disposable so there is no risk of cross contamination. The results of this study will help us decide whether this new camera might be the ideal test to detect patients with these two conditions and potentially benefit the wider population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

ref: 12/EM/0100

Study design

Non-randomised interventional and observational trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Oral and Gastrointestinal disease

Interventions

Description: 50 Barrett's cases 50 dyspepsia/heartburn controlls 50 chronic liver disease patients EG scan, ultrathin transnasal imaging endoscope followed up at 1 month.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Accuracy in diagnosing Barrett's oesophagus and oesophageal varices

Key secondary outcome(s))

Patients' acceptability

Completion date

26/11/2013

Eligibility

Key inclusion criteria

- 1. Adult participants aged 18 years or above who are referred for routine upper GI endoscopy for BO surveillance, varices surveillance and dyspepsia.
- 2. Able and willing to give informed consent.
- 3. Male and female participants
- 4. >18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Patients known to be intolerant to endoscopy
- 2. Patients with history of broken nose, deviated nasal septum or disease of the nasal cavity
- 3. Patients not clinically fit for endoscopy as judged by their caring team
- 4. Pregnant women

Date of first enrolment

Date of final enrolment 26/11/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Industry

Funder Name

Intromedic Co. Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|-------------------------|----------------|-----------------|
| Results article | results | 01/03/2019 | Yes | No |
| Participant information sheel | Participant information sheet | 11/11/2025 11/11/2025 | No | Yes |