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The E.G. Study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

26/02/2012

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