

St Mark's Conventional Endoscopy versus transNasal endoscopy Trial

Submission date 12/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/04/2014	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Protocol V 2.0

Study information

Scientific Title
St Mark's Conventional Endoscopy versus transNasal oesophagogastroduodenoscopy Trial

Acronym

SCENT

Study objectives

In a UK setting, transnasal OGD (tOGD) is non-inferior to conventional (oral) OGD (cOGD) in terms of patient safety, diagnostic capability and feasibility. We also hypothesise that tOGD is superior to cOGD in terms of patient satisfaction

Ethics approval required

Old ethics approval format

Ethics approval(s)

Harrow Research Ethics Committee (North London REC 3) on the 11/06/2008: Reference number 08/H0719/24.

Study design

Randomised controlled study (parallel design)

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Upper Gastrointestinal Endoscopy (OGD)

Interventions

1. Transnasal OGD versus conventional (oral) OGD - a comparison of two routinely performed endoscopy procedures
2. Patients received either a conventional OGD or a transnasal OGD only once and did not require any additional drugs or follow-up in relation to the study

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Patient tolerance, feasibility and safety of tOGD procedures (done using 4.9mm and 5.9mm ultrathin (UT) endoscopes) as compared to cOGD procedures (done using standard 9.0mm or UT 4.9mm and 5.9mm endoscopes)

Key secondary outcome(s)

1. Patient tolerance, feasibility and safety of tOGD procedures (done using 4.9mm UT endoscopes) as compared to tOGD procedures (done using 5.9mm ultrathin (UT) endoscopes).
2. Patient tolerance, feasibility and safety of tOGD procedures done using 4.9mm and 5.9mm ultrathin (UT) endoscopes) and cOGD procedures (done under sedation using standard 9.0mm or UT 4.9mm and 5.9mm endoscopes)

3. Patient tolerance, feasibility and safety of tOGD procedures done using 4.9mm and 5.9mm ultrathin (UT) endoscopes) and cOGD procedures (done without use of sedation using standard 9.0mm or UT 4.9mm and 5.9mm endoscopes)

Completion date

30/11/2009

Eligibility

Key inclusion criteria

1. Adult patients referred for diagnostic OGD to St Marks Hospital Endoscopy Unit
2. Patients who are able to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients who are unwilling to have a tOGD
2. Patients with a history of nasal trauma or nasal surgery
3. Patients with a history of recurrent epistaxis
4. Patients with a history of haemorrhagic tendency or who are on anticoagulation
5. Patients with a history of severe co-morbidity (especially respiratory disease) as judged by the investigators
6. Patients already participating in another trial
7. Patients lacking capacity to give informed consent

Date of first enrolment

01/09/2008

Date of final enrolment

30/11/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Wolfson Unit for Endoscopy
London
United Kingdom
HA1 3UJ

Sponsor information

Organisation
North West London Hospitals NHS Trust (UK)

ROR
<https://ror.org/04cntmc13>

Funder(s)

Funder type
Research organisation

Funder Name
Self funded by the investigators

Funder Name
Research support received from Endoscopy UK and Fujinon (Europe) in the form of loan endoscopes

Funder Name
Endoscopy Research Fellowship Grant and Keymed-Olympus (UK) in the form of loan endoscopes

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration