ISRCTN77474635 https://doi.org/10.1186/ISRCTN77474635

St Mark's Conventional Endoscopy versus transNasal endoscopy Trial

Submission date	Recruitment status	[ ] Prospectively registered
12/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2014	Digestive System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 receved 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 measure
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)

Secondary outcome measures
1. Patient tolerance, feasibility and safety of tOGD procedures (done using 4.9mm UT endoscopes)as compared to tOGD procedeures (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 procedeures (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 procedeures (done without use of sedation using standard 9.0mm or UT 4.9mm and 5.9mm endoscopes)

Overall study start date
01/09/2008

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

Age group
Adult

Sex
Both

Target number of participants
200

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
England

United Kingdom

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

Sponsor information

Organisation
North West London Hospitals NHS Trust (UK)

Sponsor details
R&D Department
Northwick Park Hospital
Watford Road
Harrow
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England
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration