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

Contact name

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Contact details

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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 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 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

Kev 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 London England United Kingdom HA1 3UJ

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