# St Mark's Conventional Endoscopy versus transNasal endoscopy Trial

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

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Chris Fraser

#### Contact details

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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**

#### **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 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(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 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)

#### 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

# **Study outputs**

Output type

Details

Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No

Yes