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Transnasal endoscopy: image quality and patient acceptability

Submission date	Recruitment status	[_] Prospectively registered
13/02/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/04/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2016	Surgery	

Plain English summary of protocol

Background and study aims
Transnasal endoscopy (TNE) is a procedure whereby a flexible tube containing a video camera (endoscope) is passed via the nose, rather than the mouth, into the stomach. Transnasal endoscopy has gained wide acceptance in Japan over the last 5 years and has increasingly been practised in Europe and North America. It has the advantage that the transnasal (nose) route does not so readily induce a gag reflex, therefore the examination can be a lot more comfortable and, furthermore, the patient can interact and speak with the endoscopist during the examination. The patient does not require staying long following the completion of the examination, because there is no risk of aspiration as there is with the traditional throat spray (lasting about 30 minutes to an hour). The aim of the study is to evaluate the role of unsedated transnasal endoscopy versus routine unsedated endoscopy under throat spray.

Who can participate?
Every patient due for a diagnostic upper gastrointestinal endoscopy under local anaesthetic.

What does the study involve?
Participants will be randomly allocated to undergo either transoral (mouth route) endoscopy or transnasal (nose route) endoscopy. Both procedures will be carried out in the same environment in a standardised manner. The same team of experienced endoscopists will perform all endoscopic examinations. The duration of the procedure will be recorded from the beginning of nasal topic anaesthetic to the withdrawal of the endoscope. In addition, both procedures will be videoscoped or representative images will be taken from key areas of the upper digestive system. The quality of the procedure in terms of being able to achieve adequate information and image quality will be recorded for both types of procedure. Image recording in endoscopy is considered standard good endoscopic practice in particular when pathology is found.

What are the possible benefits and risks of participating?
Patients who are interested to participate in the study may avoid the waiting time of their regular appointment. The study does not involve anything additional in terms of risks than standard endoscopy practice. Transoral and transnasal endoscopy are routinely used for investigation and diagnosis of upper digestive system symptoms.

Where is the study run from?
The study will take place in the Clinical Research Facility in the Royal Infirmary of Edinburgh (UK).

When is the study starting and how long is it expected to run for?
The study started in February 2011 and is anticipated to end in February 2012.

Who is funding the study?
The NHS Lothian R&D and Imotech-Fujinon fund the project.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REC No: 10/S1103/21

Study information

Scientific Title
Prospective randomized control study of the use of transnasal upper digestive endoscopy: image quality and patient acceptability

Study objectives
Transnasal endoscopy has gained wide acceptance in Japan over the last 5 years and has increasingly been practised in Europe and North America. It has the advantage that it uses a super thin (<6mm) flexible endoscope which can be introduced through the nose in an unsedated patient. It has the advantage that the transnasal route does not so readily induce a

gag reflex therefore the examination can be a lot more comfortable and, furthermore, the patient can interact and speak with the endoscopist during the examination. The patient does not require to stay long following the completion of the examination, because there is no risk of aspiration as there is with the traditional throat spray (lasting approximately 30 minutes to an hour). The examination can therefore be carried out on an ambulatory basis in Primary Care Offices and Outpatient Departments. This technique has not gained wide acceptance in the UK and at present there are very few centres routinely offering transnasal endoscopy. The aim of the study is to prospectively evaluate in a randomised manner the role of unsedated transnasal endoscopy versus routine unsedated endoscopy under throat spray.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland NHS Research Ethics Committee, 09 June 2010 ref: 10/S1103/21
NHS Lothian Research & Development Project No: 2010/RlGII01

Study design
Prospective randomised control study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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 gastro intestinal endoscopy

Interventions
Following patient consent and after recording standard demographic and clinical information, the procedure will take place in the Clinical Research Facility in the Royal Infirmary of Edinburgh. Both the trans-oral unsedated (under throat spray) endoscopy and the unsedated transnasal endoscopy will happen in the same environment in a standardised manner. The same team of experienced Endoscopists (KT/JP/PCH/SA) will perform all endoscopic examinations. The duration of the procedure will be recorded from the beginning of nasal topic anaesthetic to the withdrawal of the endoscope. In addition, both procedures will be videoscoped or representative images will be taken from key anatomical areas of the upper digestive system. These will include the oesophagus, the oesophagogastric junction, cardia (retroflexion), inspection of the body, the antrum, the incisura (lesser curve), the pylorus, D1 and D2 images. The quality of the procedure in terms of being able to achieve adequate topographic

information as well as adequate image quality of pictures will be recorded for both types of procedures. Image recording in endoscopy is considered standard good endoscopic practice in particular when pathology is found. Furthermore, images will be taken also under FICE (Fujinon Intelligent ChromoEndoscopy) from all examinations for further assessment of the FICE quality. All images will be anonymized prior to further analysis.

Following completion of the procedure and up to 72 hours, complications will be recorded by a specific questionnaire. Questionnaires regarding expectations of the procedure, procedure acceptability, and satisfaction with the examination will be used to assess the patient's experience at the end of the procedure and a week later.

For patients who have previous experience of trans-oral endoscopy, a specific questionnaire will be used, aiming to record whether they would prefer in the future to have a transnasal endoscopy or a standard endoscopy.

In all questionnaires we will use a visual analog scale (0 to 10cm) and will ask the patient to mark somewhere in between. The length from 0 to the marked point will be measured in cm and will be the score for that question.

A sub group of patients will inevitably require having their endoscopy repeated (i.e. in cases of oesophagitis to check healing or gastric ulcers to check healing etc). These people will be given the opportunity to have the repeat endoscopy in a crossover fashion i.e. those who were previously randomised to have a trans-oral endoscopy will have it done via the transnasal route while those randomised to the initial endoscopy through the transnasal route will have it in the trans-oral manner. The study will be completed for those patients who do not wish to enter the cross over phase.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Is there a difference in the acceptability (as marked on a 100mm line) in those receiving transnasal endoscopy (TNE) versus standard endoscopy?

Secondary outcome measures
1. Is there a difference in the tolerability (as marked on a 100mm line) in those receiving TNE versus standard endoscopy?
2. Is there a difference in the acceptability / tolerability of each method (TNE and standard) in those patients who receive both methods in the course of this trial?
3. Adequacy of endoscopic examination and image quality of endoscopic images including digital image enhancement (FICE). The endoscopist will be asked to comment using a specific questionnaire along the lines explained in A10

Overall study start date
01/09/2010

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. Routine indication for diagnostic upper GI endoscopy
2. Age over 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250 participants

Key exclusion criteria
1. Patients who demand an under sedation upper endoscopy
2. Pregnant women
3. Patients with any malformation of nasal area or previous nose surgery or fractures
4. History of frequent nose bleeds or blood coagulopathy
5. Patients receiving warfarin
6. Psychiatric disorders
7. Patient allergic to the local anaesthetic used
8. High risk for Variant Creutzfeldt-Jakob disease (vCJD) patients

Date of first enrolment
01/09/2010

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

University of Edinburgh
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
The Queens Medical Research Institute
47 Little France Crescent
Edinburgh
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United Kingdom
EH16 4TJ

Sponsor type
University/education

Website
http://www.ed.ac.uk/

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
University/education

Funder Name
University of Edinburgh (UK)

Alternative Name(s)
Universitas Academica Edinburgensis, Oilthigh Dhùn Èideann, The University of Edinburgh, University of Edinburgh in United Kingdom, Edin, Tounis College, King James' College, Athens of the North, ED, Edin

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
United Kingdom

Funder Name
Imotech (UK) - Fujinon

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results:	01/09/2014		Yes	No