

Walk in nasal endoscopy (WINES) study: a pilot evaluation of the safety and feasibility, and cost savings of introducing a radically new approach to upper gastrointestinal (GI) endoscopy

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/12/2014	Condition category Cancer	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0077132412

Study information

Scientific Title

Walk in nasal endoscopy (WINES) study: a pilot evaluation of the safety and feasibility, and cost savings of introducing a radically new approach to upper gastrointestinal (GI) endoscopy

Study objectives

Evaluation of safety and feasibility of a walk in two week cancer waiting list upper GI endoscopy using nasal endoscope and only one assistant. A single consultant ATC doing the procedures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Cancer: Gastrointestinal

Interventions

Nasal endoscopy is currently performed in the endoscopy unit at Derby City General Hospital but in a procedure analogous to conventional endoscopy using two nurse assistants. The study will be a pilot randomised controlled study comparing conventional with nasal (ultraslim endoscopy) to assess primarily the safety and feasibility of performing nasal endoscopy with just one assistant and the patient in a seated position.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary endpoints will be the proportion of cases in which this procedure could be performed and the number of early to late (within 1 week) complications. Assessment of safety will be by pro forma records of complications during endoscopy and prior to discharge and by using a patient questionnaire administered 1 week later.

The endoscopist will assess the feasibility of the nasal procedure. Completeness of endoscopy and visualisation of the duodenum, antrum, body and fundus of the stomach and oesophagus will be recorded.

Secondary outcome measures

Secondary endpoints will be a questionnaire of the patients acceptability of the procedure and a preliminary assessment of the savings in staff costs of this procedure.

Overall study start date

21/10/2003

Completion date

01/12/2004

Eligibility

Key inclusion criteria

Patients attending for endoscopy through two-week cancer waiting list.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

21/10/2003

Date of final enrolment

01/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Southern Derbyshire Acute Hospitals NHS Trust

Derby

United Kingdom

DE22 3NE

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Southern Derbyshire Acute Hospitals NHS Trust (UK)

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