

A randomised controlled study of patients seen in a special nurse-led clinic after gastroscopy investigation for symptoms related to indigestion

Submission date 27/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/04/2008	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Praful Patel

Contact details
Southampton University Hospital NHS Trust
Department of Gastroenterology
Level D
West wing
Southampton
United Kingdom
SO16 6YD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RHM MED0719

Study information

Scientific Title

A randomised controlled trial of structured nurse-led clinic follow-up for dyspeptic patients after direct access gastroscopy

Study objectives

The aim is to study patients with a confirmed endoscopic diagnosis of the following:

1. Mild gastro oesophageal reflux disease (non-erosive and mild oesophagitis)
2. Hiatus hernia (any size)
3. Non-ulcer dyspepsia (normal findings, mild or moderate gastritis and duodenitis)

Study hypothesis:

An experienced gastrointestinal nurse practitioner providing structured patient-centred advice at follow-up clinic after gastroscopy to patients with mild dyspepsia, would reduce drug costs without adversely affecting symptoms relief or quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton & South West Hampshire Research Ethics Committees (B). Date of approval: 22nd March 2002 (REC reference: 050/02)

Study design

Single-centre, randomised, placebo-controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Gastroscopy

Interventions

This is a randomised placebo-controlled trial with concealed allocation (random number table) of study cohorts. Post-intervention assessor is blinded to diagnosis and study status.

Baseline data collection:

1. Demography
2. Body mass index (BMI)
3. Social habit status
4. Ulcer healing drugs (UHD; Histamine 2 antagonist, proton pump inhibitor) used in the 6 months before investigation
5. Glasgow dyspepsia severity score (GLADYS)
6. Health related general well being (12-item short form health survey [SF-12])

After gastroscopy, eligible patients are randomised to either normal (control) practice (return to GP for follow-up treatment) or intervention (to nurse follow-up).

The nurse-led clinic last for 35 minutes and a full medical history is taken. The clinical management is based on national and local guidelines, with reference to findings as well as patients' predominant symptoms. Counselling and lifestyle advice, including bespoke information leaflets given and treatment concordance agreed; further investigation may be initiated if required. For consistency and reproducibility 'History taking' and 'Lifestyle advice' proformas are devised for use. Clinic letter with information on intervention and treatment recommendations is sent to patients' GP after consultation.

Six months after gastroscopy all patients are contacted by telephone for reassessment of the following:

1. Weight
2. GLADYS
3. SF-12
4. UHD used in the six months after gastroscopy
5. Usefulness of post-investigation follow-up

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The difference between the nurse group and GP group after intervention in:

1. GLADYS: 8 questions and a total low score equals to least symptoms with a minimum of 0 and maximum 20
2. SF-12: Six questions (3 have 2 parts and 1 has 4 parts). A total high score in this measurement denotes better health related general well being with a minimum 0 and maximum 900
3. UHD costs 6 months before and after gastroscopy. The UHD cost analysis is based on the price listed in the Drug Tariff (generic items) or MIMS (branded items). They are summed according to class and averaged.

Secondary outcome measures

Compares before and after intervention within same group in:

1. GLADYS
2. SF-12
3. UHD costs

Overall study start date

01/02/2003

Completion date

28/02/2005

Eligibility

Key inclusion criteria

1. Male and female patients with dyspepsia
2. Over 18 years old
3. Undergoing direct access gastroscopy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

186

Key exclusion criteria

There are 2 stages of filtering for exclusion as follows:

1. Before gastroscopy - From referral letters/forms patients with sinister symptoms:
 - 1.1. Anaemia
 - 1.2. Weight loss over half a stone in three months
 - 1.3. Haematemesis
 - 1.4. Dysphagia
 - 1.5. Vomiting
2. After gastroscopy:
 - 2.1. Peptic ulcer
 - 2.2. Tumour
 - 2.3. Severe oesophagitis
 - 2.4. Barrett's oesophagus
 - 2.5. Anatomical abnormality and
 - 2.6. Post-operative stomach

Date of first enrolment

01/02/2003

Date of final enrolment

28/02/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Southampton University Hospital NHS Trust

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

Sponsor details

Research and Development Department

Trust Management Office

Mailpoint 18

Treamona Road

Southampton

England

United Kingdom

SO16 6YD

Sponsor type

Hospital/treatment centre

Website

<http://www.suht.nhs.uk>

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Other

Funder Name

This study was investigator-funded with the agreement of the Southampton University Hospital NHS Trust that secretarial and out-patient work force can be utilised as long as it is planned into routine work.

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	01/04/2006		Yes	No