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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/04/2008	**Overall study status** Completed	
Last Edited 02/04/2008	**Condition category** Digestive System	

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
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
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Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

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Research and Development Department
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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