ISRCTN87644265 https://doi.org/10.1186/ISRCTN87644265

A multicentre randomised controlled trial of C13-Urea Breath testing and Helicobacter pylori eradication for dyspepsia in primary care

Submission date 02/05/2001	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/05/2001	**Overall study status** Completed	
Last Edited 31/03/2009	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://pcpoh.bham.ac.uk/primarycare/research/cube/

Contact information

Type(s)
Scientific

Contact name
Dr Brendan Delaney

Contact details
Department of Primary Care & General Practice
The Medical School
Edgbaston
Birmingham
United Kingdom
B15 2TT
b.c.delaney@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0001078

Study information

Scientific Title

Acronym
CUBE

Study objectives
1. To determine the cost-effectiveness of an H. pylori 'test and trust' strategy compared with initial acid suppression for the initial management of dyspensia in primary care
2. To determine the influence of selected patients on the basis of predominant heartburn or epigastic pain
3. To determine the performance of the H. pylori stool antigen (HpSA) test for H. pylori compared with a C13 Urea breath test for confirming H. pylori eradication in primary care

Please note that the target number of participants was added as of 06/03/2008.

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)
GP practice

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Dyspepsia in primary care

Interventions
All patients - will receive omeprazole 20mg once daily.

Study Group - C13 Urea breath test for H. pylori, using a test kit performed by the practice nurse. Patients testing positive will be offered H. pylori eradication with clarithromycin 250 mg twice daily and metronidazole 400 mg twice daily in addition to omeprazole. Patients testing negative will continue PPI (omeprazole).

Control Group - Patients will continue 4/52 PPI (omeprazole).

After four weeks patient management will be at the discretion of the general practitioner (GP). Patients receiving H. pylori eradication will be contacted by research staff and asked to attend for a follow-up breath test and produce a stool sample (for the stool antigen test) nine weeks after entry.
Follow-up will be by postal questionnaire at 12 weeks, interview at one year and a GP notes review (conducted by research staff).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
omeprazole, clarithromycin, metronidazole

Primary outcome measure
1. Effects measured as absolute risk reduction for dyspeptic symptoms measured by the Short Form Leeds Dyspepsia score, a validated community-based measure that also includes a question on 'predominant symptoms'.
2. Health service related dyspepsia costs as determined by application of national reference costs to individual units of resource consumption (prescribing, consultations, interventions and investigations).

Secondary outcome measures
1. Quality of life using Euro-QoL instrument (EQ-5D).
2. Patient satisfaction using the consultations Satisfaction Score (subscales one and two, general and professional care)
3. Performance of HpSA test

Overall study start date
01/03/2002

Completion date
28/02/2006

Eligibility

Key inclusion criteria
All patients age 18-65 years consulting GP with dyspepsia (either with a new episode or for follow up).

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Target number: 2000; Number actually enrolled: 699

Key exclusion criteria
1. Knowledge of previous test for H. pylori.
2. Patients who have a history suggestive of gastric cancer.i.e. dysphagia, weight loss, haematemesis or malaena, first-degree relative with gastric cancer.
3. Patient age 55-65 with continuous as opposed to episodic epigastric pain or a total history of any dyspeptic symptoms of less than a year at presentation (in accord with the National Health Service two week suspected cancer referral guidelines).
4. Knowledge of endoscopically proven peptic ulcer disease or severe oesophagitis (who should all receive either eradication therapy (ulcer) or proton pump inhibitor (oesophagitis)
5. Pregnant women
6. Patients who are unable to give informed consent
7. Patients taking regular non-steroidal anti-inflammatory drugs (who might have NSAID induced ulcers),or having started aspirin 75 - 150 mg in the past three months
8. Patients allergic to study drugs
9. Residents of USA or Canada

Date of first enrolment
01/03/2002

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care & General Practice
Birmingham

United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

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

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	22/03/2008		Yes	No