ISRCTN10740230 https://doi.org/10.1186/ISRCTN10740230

Evaluation of H. pylori infection in aspirin users - pilot study

Submission date	Recruitment status	[_] Prospectively registered
07/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2015	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G0700648

Study information

Scientific Title
Helicobacter pylori Eradication vs Aspirin Toxicity pilot study

Acronym

HEAT

Study objectives
Eradication of H. pylori in patients taking aspirin regularly will reduce the risk of ulcer bleeds.

More details can be found at: http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0700648&CaseId=9889

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham 2 Research Ethics Committee, 21/09/2007

Primary study design
Interventional

Study design
Part 1: Interventional, non-randomised controlled study. Part 2: Observational database study.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ulcer bleeding

Interventions
This trial has two parts:

Part 1: Interventional study. This study will establish the H. pylori infection rates and success of eradication therapy.

GPs will screen their patient records for potential participants (Aged >45 and on <300 mg aspirin /day, excluding ulcer healing drugs and NSAIDs) and write to them to invite them to take part in the study. All participants will have a 13C Urea breath test (to establish their H. pylori status) and a blood sample taken (for future H. pylori serology testing). For participants who test negative for H. pylori, this will be the end of their involvement in the study. All patients who test positive for H. pylori (there will be no randomisation) will be given eradication therapy (Clarithromycin 500 mg twice a day [bd], omeprazole 20 mg bd and metronidazole 400 mg bd. Eradication treatment will last 7 days), and retested 6-8 weeks later to test eradication success.

Part 2: Observational study. This is a database study to assess aspirin use in the target population and rates of ulcer bleeds.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Clarithromycin, omeprazole, metronidazole

Primary outcome(s)
1. Rate of aspirin use (results of Part 2 Observational study)
2. Rate of ulcer bleeding in patients using aspirin (results of Part 2 Observational study)
3. Level of H. pylori infection and subsequent eradication rates in aspirin patients at 6-8 weeks after the eradication therapy
4. Level of interest from GPs and patients for a randomised study and their preferred enrolment site

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/07/2008

Eligibility

Key inclusion criteria
1. Male and female patients aged 45 years of age or older
2. Patients who have given written informed consent
3. Patients taking aspirin (less than or equal to 300 mg daily)
NB: Patients who have previously been tested for H. pylori and/or had previous eradication therapy will not be excluded.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients currently taking anti-ulcer therapy (H2-receptor antagonists i.e. cimetidine, famotidine, nizatidine or ranitidine and Proton Pump Inhibitors [PPIs] i.e. esomeprazole, lansoprazole, omeprazole, pantoprazole or rabeprazole sodium)
2. Patients currently taking non-selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (aceclofenac, acemetacin, azapropazone, dexibuprofen, dexketoprofen, diclofenac sodium, diflunisal, fenbufen, fenoprofen, flurbiprofen, ibuprofen, indometacin, ketoprofen, mefenamic acid, meloxicam, nabumetone, naproxen, piroxicam, sulindac, tenoxicam, or tiaprofenic acid)
3. Patients who are terminally ill
4. Patients who are allergic to any of the eradication treatment drugs
5. Patients who are currently being treated with an antibacterial or have had antibacterial

treatment within the last 4 weeks
6. Patients who have had treatment with a PPI (listed above) within the last 2 weeks.
7. Women who are pregnant or breast feeding

Date of first enrolment
01/02/2008

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wolfson Digestive Diseases Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	10/07/2015		Yes	No