

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

<b>Submission date</b> 07/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/10/2015	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Chris Hawkey

**Contact details**  
Wolfson Digestive Diseases Centre  
University Hospital  
Nottingham  
United Kingdom  
NG7 2UH  
+44 (0)115 8231033  
cj.hawkey@nottingham.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Study design

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

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 <sup>13</sup>C 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 measure**

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

### **Secondary outcome measures**

No secondary outcome measures

### **Overall study start date**

01/02/2008

### **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

### **Age group**

Adult

**Sex**

Both

**Target number of participants**

905

**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**

England

United Kingdom

**Study participating centre**

**Wolfson Digestive Diseases Centre**

Nottingham

United Kingdom

NG7 2UH

**Sponsor information****Organisation**

University of Nottingham (UK)

**Sponsor details**

Research Innovation Services  
King's Meadow Campus  
Lenton Lane  
Nottingham  
England  
United Kingdom  
NG7 2NR  
+44 (0)115 9515679  
paul.cartledge@nottingham.ac.uk

**Sponsor type**

University/education

**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, 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?
<a href="#">Results article</a>	results	10/07/2015		Yes	No