

# 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

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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

### **Study design**

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

### **Primary study design**

Interventional

### **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 <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(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

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