

Helicobacter Eradication Aspirin Trial (HEAT)

Submission date 19/12/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/08/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Aspirin is a medicine that reduces the risk of clots forming in your blood. Aspirin use is widespread and increasing in elderly patients. The main side effect is gastrointestinal (digestive tract) bleeding, the incidence of which is rising, probably because of increased aspirin use. We think that the bacterium *Helicobacter pylori* causes stomach ulcers and aspirin, by thinning the blood, makes the ulcers bleed. If the bacterium is eradicated the patient will not get an ulcer and therefore there is no increased bleeding risk with aspirin. The aim of this study is to find out whether a one-week course of *H. pylori* eradication will reduce the rate of hospitalisation due to ulcer bleeding.

Who can participate?

Patients over 60 using aspirin daily who are infected with *H. pylori*.

What does the study involve?

Participants are randomly allocated to either treatment to eradicate *H. pylori* or placebo (dummy tablets). There will be no follow-up visits for 90% of patients. Instead we will use GP electronic databases to identify hospital admissions for ulcer bleeding. A random sample of participants will be breath tested at the end of the study to ensure that we are achieving similar *H. pylori* eradication rates to those achieved in our previous study.

What are the possible benefits and risks of participating?

A positive result would increase patient safety, reduce hospitalisations for gastrointestinal bleeding, reduce premature death, decrease medical costs and expand the number of patients for whom aspirin is beneficial.

Where is the study run from?

Nottingham Digestive Diseases Centre (UK)

When is the study starting and how long is it expected to run for?

March 2012 to December 2021 (updated 14/01/2021, previously: April 2017)

Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-003425-96

ClinicalTrials.gov (NCT)
NCT01506986

Protocol serial number
11091

Study information

Scientific Title

Helicobacter eradication to prevent ulcer bleeding in aspirin users: a large simple randomised controlled trial

Acronym

HEAT

Study objectives

Current hypothesis as of 25/05/2016:

A one week course of Helicobacter pylori (H. pylori) eradication in patients using aspirin (less than 325mg) daily will reduce the incidence of subsequent adjudicated peptic ulcer bleeding which results in hospitalisation.

Previous hypothesis:

A one week course of Helicobacter pylori (H. pylori) eradication in patients using aspirin (325mg) daily will reduce the incidence of subsequent adjudicated peptic ulcer bleeding which results in hospitalisation.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/095552>

Protocol can be found at: http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0006/54555/PRO-09-55-52.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

East Midlands Research Ethics Committee, 08/12/2011, ref: 11/EM/0434

Study design

Double-blind placebo-controlled randomised multi-centre study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients using aspirin less than 325mg daily

Interventions

Active treatment will consist of seven days of lansoprazole 30mg, clarithromycin 500mg and metronidazole 400mg all given twice daily. This is one of the authorised recommended regimens for H. pylori eradication in adults. The control group will receive placebos to the same regimen:

Lansoprazole (CAS: 103577-45-3); 30mg capsules (generic)

Clarithromycin (CAS: 81103-11-9); 500mg tablets (generic)

Metronidazole (CAS: 99616-64-5); 400mg tablets (generic)

Current interventions as of 25/05/2016:

The trial will continue until 87 adjudicated events have occurred, which would occur after a mean 2.5 patient years of follow-up, if trial assumptions are correct.

Previous interventions:

The trial will continue until 96 adjudicated events have occurred, which would occur after a mean 2.5 patient years of follow-up, if trial assumptions are correct.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Clarithromycin, lansoprazole, metronidazole

Primary outcome(s)

The rate of hospitalisation due to peptic ulcer bleeding in patients who enter the randomised study (only the first event per patient will be analysed), adjudicated by a blinded committee as definite or probable. The committee will use definitions validated in the TARGET study.

Key secondary outcome(s)

1. Other causes of GI bleeding (adjudicated); these are predicted not to be affected by H. pylori eradication and will act as a specificity control
2. Cardiovascular outcomes (APTC endpoint, MI and stroke, unadjudicated); these are predicted not to be affected
3. The incidence of detected uncomplicated ulcers
4. Ulcer site (Duodenal Ulcer vs. Gastric Ulcer)
5. GP-recorded and patient-reported dyspepsia
6. Need for PPI prescription or other antiulcer/dyspepsia medication

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. Males and females more than 60 years of age at the date of screening
2. Subjects who are taking aspirin less than 325mg daily and who have had 4 or more 28 day prescriptions in the last year
3. Subjects who are concurrently using other anti-platelet agents are allowed to enter the study
4. Subjects who are willing and able to undergo a breath test for H. pylori, including fasting for 6 hours, and whose result is unequivocally positive (results of breath test will be determined post-screening)
5. Subjects who are willing to give permission for their paper and electronic medical records to be accessed and abstracted by trial investigators
6. Subjects who are willing to be contacted and interviewed by trial investigators, should the need arise for adverse event assessment, etc
7. Subjects must be able to communicate well with the investigator or designee, to understand and comply with the requirements of the study and to understand and sign the written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

30166

Key exclusion criteria

1. Subjects who are currently prescribed anti-ulcer therapy such as H2-receptor antagonists and proton-pump inhibitors
2. Subjects who are currently prescribed oral non-steroidal anti-inflammatory drugs (NSAIDs)
3. Subjects who have a known intolerance or allergy to H. pylori eradication treatment
4. Subjects who are taking drugs with a clinically significant interaction with H. pylori eradication treatment
5. Subjects who are terminally ill or suffer from a life-threatening co-morbidity
6. Subjects whose behaviour or lifestyle would render them less likely to comply with study medication (eg. alcoholism, substance abuse, debilitating psychiatric conditions or inability to provide informed consent)
7. Subjects currently participating in another interventional clinical trial or who have taken part in a trial in the previous three months

Date of first enrolment

01/03/2012

Date of final enrolment

01/04/2017

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Study participating centre

Nottingham Digestive Diseases Centre

Nottingham

United Kingdom

NG7 2UH

Study participating centre
University of Southampton
United Kingdom
SO17 1BJ

Study participating centre
Durham University
United Kingdom
DH1 3LE

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University of Oxford
United Kingdom
OX1 2JD

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University of Birmingham
United Kingdom
B15 2TT

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Queens University Belfast
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BT7 1NN

Sponsor information

Organisation
University of Nottingham (UK)

ROR
<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme (UK) ref: 09/55/52

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/11/2022	13/06/2023	Yes	No
Results article		23/08/2025	27/08/2025	Yes	No
Protocol article	protocol	10/07/2015		Yes	No
HRA research summary			28/06/2023	No	No