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| **Study Title: HEAT: Helicobacter Eradication Aspirin Trial** |
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| **Study Co-ordinator: Rachel Iles Tel: 0121 414 2691 or email** **r.iles@bham.ac.uk** |
| **Chief Investigator: Professor Christopher Hawkey** |
| **Funders: NIHR HTA** |
| **Sponsor: University of Nottingham** |
| **Study Aims:** **HEAT is a large simple double-blind placebo controlled outcomes study of *Helicobacter pylori* (*H.pylori*) eradication to prevent ulcer bleeding in aspirin users.** **Aspirin use is widespread and increasing in elderly patients. The main hazard is gastrointestinal bleeding, which may be increasing because of increasing aspirin use. This trial is based on evidence that peptic ulcer bleeding in aspirin users occurs predominantly in *H. pylori* positive people.****Primary endpoint is rate of hospitalisation due to definite or probable peptic ulcer bleeding.** |
| **Study Activity:****Once identified by their GPs, patients will be invited to attend an appointment with a Research or Practice Nurse for informed consent and to take an *H. pylori* breath test.** **Those with a positive result will be randomised to receive a one week course of either eradication treatment or placebo, which will be sent by post by the trial team.****Patients will be followed up for 2 years by the trial team. An annual notes check but no follow-up practice visits will be required.** |
| **Number of Patients Needed: 10,000 nationally** |
| **Target in West Midlands South: 100 patients/practice approximately** |
| **Practice Involvement in the Study:*** **Clinical System search for eligible patients using MIQUEST;**
* **Mail merge letter of invitation to eligible patients and reminders where necessary;**
* **Provision of a room and facilities for research nurse to conduct baseline clinics (no subsequent research clinics will be required as patients are seen only at baseline by the research nurse);**
* **A named GP to lead the study within the practice as “Site Study Coordinator;**
* **Lead GPs to be on site when nurses are consenting patients/ conducting baseline clinics;**
* **Notes check for participating patients after one year.**
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| **Inclusion Criteria: Patients who are:*** **≥ 60 years of age at the date of screening;**
* **Taking aspirin ≤325mg daily and who have had 4 or more 28-day prescriptions in the last year;**
* **Concurrently using other anti-platelet agents are allowed to enter the study;**
* **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);**
* **Willing to give permission for their paper and electronic medical records to be accessed and abstracted by trial investigators;**
* **Willing to be contacted and interviewed by trial investigators, should the need arise for adverse event assessment, etc.;**
* **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.**
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| **Exclusion Criteria: Patients who are:*** **Currently taking anti-ulcer therapy such as H2-receptor antagonists and proton-pump inhibitors;**
* **Currently taking non-steroidal anti-inflammatory drugs (NSAIDs);**
* **Known intolerance or allergy to *H. pylori* eradication treatment;**
* **Taking drugs with a clinically significant interaction with *H. pylori* eradication treatment**
* **Terminally ill or suffer from a life-threatening co-morbidity;**
* **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). Currently participating in another interventional clinical trial or who have taken part in a trial in the previous three months.**
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| **Reimbursement: Total amount will vary dependent on whether a research nurse (£1,768 based on 100 patients) or practice nurse (£2,766 based on 100 patients) conducts baseline clinics** |
| **For further details please contact:** **p.darbyshire@warwick.ac.uk** |

**Thank you for your interest in this study**