

Can eradicating a common stomach bug make taking aspirin safer?

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Researchers have launched a major clinical trial to investigate whether eliminating a common stomach bug could help to make taking aspirin safer in some patients.

The *Helicobacter* Eradication Aspirin Trial (HEAT) will look at whether wiping out the bacterium <u>Helicobacter pylori</u> in the gut of <u>patients</u> taking up to 325mg of aspirin a day could reduce their chances of developing a stomach ulcer and dangerous associated bleeding — a complication which kills thousands of people every year.

One of the largest of its kind, it's estimated that the study, being led by The University of Nottingham in collaboration with academics at the Universities of Durham, Southampton, Oxford and Birmingham, will recruit in the region of 10,000 aspirin patients found to be infected with *H. pylori*.

Professor Chris Hawkey of the Nottingham Digestive Diseases Centre said "Aspirin has many health benefits. Ulcer bleeding is one of its main drawbacks. If eradicating *H. pylori* reduces this, it will be a major step forward. We are also excited about the new way we are doing this trial. By using electronic record linkage to follow patients up we reduce the burden on the patient and the cost of the trial, so that we can ask big important questions that previously only the pharmaceutical industry could afford."

More than three million people aged 60 and over in England who are at



high risk of heart attack and stroke take a dose of aspirin between 75mg and 300mg every day as an anti-clotting agent to reduce this risk.

Around 10 years ago, aspirin use was identified as the commonest cause of gastric duodenal or peptic ulcer bleeding. Since then, its use has risen by 75 per cent in the UK, accompanied by an increase in the incidence of ulcer bleeding.

Aspirin is so widely used that it has become the commonest cause of ulcer bleeding. In 2007, peptic ulcers killed almost 3,000 people in England and Wales, principally through bleeding, and in the same year, stomach ulcers saw almost 13,000 people admitted to hospital in England, at an estimated cost to the NHS of more than £10,000 per patient.

Previous studies have suggested that low dose aspirin is more likely to cause ulcer bleeding in patients infected with *H. pylori*. An endoscopy study revealed that patients with the bug were five-times more at risk of developing a stomach ulcer than their *H. pylori*-free counterparts. The new HEAT trial will cover a geographical area covering almost half the population of England, with the hope that GPs will identify in the region of 120,000 people who could potentially take part and invite them to participate in the study.

The research team expect to hear back from around 40,000 patients, around one-quarter of whom are likely to already be infected by the *H. pylori* bacterium, diagnosed through a simple breath test.

Infected patients will either be given a course of medication aimed at eradicating the infection or a placebo, while continuing to take their aspirin, and will be followed up by the research team over a period of two to three years to establish whether the patient has gone on to develop a stomach ulcer after receiving the treatment.



At the end of the trial, the team will compare the results to establish whether those who received the medication developed fewer stomach ulcers and gastric bleeds than those who received the placebo.

The study will allow them to more accurately establish whether eliminating *H. pylori* in patients taking <u>aspirin</u> reduces the risk of serious medical complications due to <u>stomach ulcers</u> and bleeds and reduces the multi-million pound burden on the NHS through treating them.

Provided by University of Nottingham

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