

Prevention of oesophageal, gastric, and duodenal lesions in patients taking anti-thrombotic low-dose aspirin with famotidine

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
08/10/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
26/10/2005	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
13/07/2009	Digestive System	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

Asp-Fam-01/ Version 3

Study information

Scientific Title

FAMOTidine for the prevention of peptic UlcerS in users of low-dose aspirin: a placebo-controlled prospective trial

Acronym

FAMOUS Trial

Study objectives

Given its efficacy against peptic ulcers induced by conventional non-steroidal anti-inflammatory drugs (NSAIDs), famotidine 40 mg daily might also be effective against upper gastrointestinal (GI) side effects of low-dose aspirin.

Please note that as of 11/02/2009 this record was updated to include amended trial dates. The initial trial dates at the time of registration were:

Initial anticipated start date: 01/01/2006

Initial anticipated end date: 01/07/2009

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 11/02/2009: NHS Ayrshire and Arran Research Ethics Committee gave approval on the 17th January 2005 (ref: 587-MAR04C)

Study design

Randomised double blind placebo controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Oesophageal, gastric and duodenal ulcers

Interventions

Interventions: famotidine 40 mg versus placebo

Screening: clinical and endoscopic assessment to identify patients who satisfy the inclusion and exclusion criteria. Clinical assessment at 6 weeks. Clinical and endoscopic assessment at 12 weeks.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Aspirin, famotidine

Primary outcome(s)

To study the effect of Famotidine 40 mg daily versus placebo for up to 3 months for the prevention of oesophageal, gastric, and duodenal ulcers in subjects taking low-dose aspirin for its anti-thrombotic effect.

Key secondary outcome(s)

1. To study the effect of Famotidine 40 mg daily versus placebo for up to 3 months for the prevention of oesophageal, gastric, and duodenal erosions and submucosal haemorrhages in subjects taking low-dose aspirin for its anti-thrombotic effect
2. To study the effect of Famotidine 40 mg daily versus placebo for up to 3 months for the treatment or prevention of symptoms of acid reflux or ulcer-like dyspepsia in subjects taking low-dose aspirin for its anti-thrombotic effect

Completion date

01/09/2008

Eligibility

Key inclusion criteria

1. Adult patients aged 18 years or over (either sex) and requiring low-dose aspirin, 75 - 325 mg daily
2. The presence of a stable and controlled indication for the anti-thrombotic effect of aspirin. This includes stable angina, previous myocardial infarction (12 or more weeks before recruitment), and peripheral vascular disease
3. The use of aspirin is likely to continue for 3 months or longer
4. The presence or absence of mild to moderate bearable dyspeptic or reflux symptoms
5. The presence or absence of gastric or duodenal erosions at base-line endoscopy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Any of the following is regarded as criterion for exclusion from the study:

1. History of oesophageal, gastric or duodenal surgery, excluding simple closure of an ulcer or vagotomy
2. Current or historical evidence of any of the following diseases:
 - 2.1. Zollinger-Ellison syndrome
 - 2.2. Primary oesophageal motility disorder(s) i.e. achalasia, scleroderma, primary oesophageal spasm
 - 2.3. Evidence of upper GI malignancy at the pre-study endoscopy
 - 2.4. Malabsorption
- 2.5. Significant cardiovascular, pulmonary, renal, pancreatic or liver disease as judged by the investigator to interfere with the evaluation of the study

- 2.6. Unstable diabetes mellitus (stable diabetes controlled by diet, oral agents or insulin is not an exclusion criterion)
- 2.7. Cerebrovascular disease such as cerebral ischaemia, infarction, haemorrhage or embolus as judged by the investigator to interfere with the evaluation of the study
- 2.8. Erosive oesophagitis at base-line endoscopy
- 2.9. Gastric ulcer and/or duodenal ulcer at base-line endoscopy or within the last 3 months
- 2.10. Inflammatory bowel disease
- 3. Suspected or confirmed current malignancy, except minor superficial skin disease
- 4. Complications related to gastroesophageal reflux disease (GORD) such as oesophageal stricture or confirmed low/high grade dysplasia of the oesophagus
- 5. Pregnancy or lactation. Women of childbearing potential will be required to maintain effective contraception during the study period as judged by the investigator.
- 6. Use of proton pump inhibitors, H2 receptor antagonists, or sucralfate within a week of the initial endoscopy
- 7. Treatment with a recognised H.pylori eradication regimen in the 28 days prior to Visit 1
- 8. Use of any other investigational compound or participation in another clinical trial within the 90 days prior to start of study medication
- 9. Need for continuous concomitant therapy with:
 - 9.1. Anticholinergics (excluding eye drops and inhaled anticholinergics)
 - 9.2. Cisapride
 - 9.3. Prostaglandin analogues
 - 9.4. Warfarin
 - 9.5. High dose steroids (more than 7.5 mg of prednisolone or its equivalent daily)
 - 9.6. Cytotoxic drugs
 - 9.7. Non-steroidal anti-inflammatory drugs
 - 9.8. Bisphosphonates used in the treatment or prevention of osteoporosis
- 10. Alcohol and/or drug abuse or any condition associated with poor compliance including expected non-cooperation, as judged by the investigator
- 11. Previous participation in this study
- 12. Contraindications to study drugs e.g. known or suspected allergy to famotidine
- 13. Need for interpreter (patients must be able to understand and complete the questionnaires in English)

Date of first enrolment

26/04/2006

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Crosshouse Hospital

Kilmarnock

United Kingdom
KA2 0BE

Sponsor information

Organisation

Greater Glasgow NHS Board (UK)

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Industry

Funder Name

Yamanouchi Corporation (Japan)

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?
Results article	results	11/07/2009		Yes	No