

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

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

**Contact name**  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet****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 measure**

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.

**Secondary outcome measures**

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

**Overall study start date**

26/04/2006

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

## **Target number of participants**

700 patients: 350 to take famotidine and 350 to take placebo

## **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**

Scotland

United Kingdom

**Study participating centre****Crosshouse Hospital**

Kilmarnock

United Kingdom

KA2 0BE

## Sponsor information

**Organisation**

Greater Glasgow NHS Board (UK)

**Sponsor details**

C/O Dr Judith Godden

West Research Office

Ground Floor Room 9

Western Infirmary

Glasgow

Scotland

United Kingdom

G11 6NT

**Sponsor type**

Hospital/treatment centre

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Yamanouchi Corporation (Japan)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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	11/07/2009		Yes	No