ISRCTN96975557 https://doi.org/10.1186/ISRCTN96975557

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

Submission date 08/10/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/10/2005	**Overall study status** Completed	
Last Edited 13/07/2009	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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?
Results article	results	11/07/2009		Yes	No