

Gaviscon Advance® versus milk of magnesia pH-impedance study

Submission date 18/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/08/2014	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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
09/H0802/112

Study information

Scientific Title

An assessment of combined pH-impedance monitoring for clinical studies of 'Gaviscon Advance®' in gastro-oesophageal reflux disease

Study objectives

The study hypothesis is that Gaviscon Advance®:

1. Will not impair the sensitivity of pH-impedance monitoring in vitro or in vivo
2. Suppresses both non-acid and acid reflux (distal and proximal reflux events) assessed by pH-impedance over a 4-hour period after a standardised test meal and over 24-hour ambulatory monitoring
3. Reduces the presence of pepsin in expectorated saliva 4 hours after a test meal

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled double-blind cross-over trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Oesophageal reflux

Interventions

Gaviscon Advance® or Milk of Magnesia will be provided during 28-hour pH-impedance monitoring. The study takes 28 hours in total; a 4-hour ambulatory pH-impedance study followed by a 4-hour observation after a meal with the catheter in situ. The study terminates when the catheter is withdrawn. There will be no follow-up thereafter.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Gaviscon Advance®, milk of magnesia

Primary outcome measure

Gaviscon Advance®:

1. Will not impair the sensitivity of pH-impedance monitoring in vitro or in vivo
2. Will suppress both non-acid and acid reflux (distal and proximal reflux events) assessed by pH-impedance over a 4-hour period after a standardised test meal and over 24-hours ambulatory monitoring
3. Reduces the presence of pepsin in expectorated saliva 4 hours after a test meal

In both in vitro and in vivo studies the effects of 'Gaviscon Advance®' will be compared to another over-the-counter antacid (Milk of Magnesia) that does not exhibit raft-forming properties (a characteristic unique to Gaviscon Advance® in which a roof is formed above gastric contents thereby preventing reflux). This is measured as soon as the catheter is withdrawn and the information on the received is downloaded. It is part of the routine analysis performed by the proprietary software for pH-impedance.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/06/2010

Completion date

01/06/2011

Eligibility**Key inclusion criteria**

1. Aged between 18 and 65 years, either sex
2. History of reflux symptoms (heartburn, acid regurgitation, chest pain) requiring referral for oesophageal manometry and pH studies
3. Patients with chronic cough or dental problems are not excluded from the trial; however, typical reflux symptoms must be present also. This is because there is little evidence that reflux events are responsible for symptoms in this group
4. Provision of written, fully informed consent to undergo mechanistic study procedures

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Significant gastrointestinal symptoms or disease other than reflux
2. Large hiatus hernia (greater than 3 cm)
3. Severe reflux oesophagitis or Barrett's oesophagus on endoscopy (Los Angeles [LA] classification grade III - IV)
4. Previous upper gastrointestinal (GI) surgery or interventions such as oesophageal dilatations
5. Predominant symptoms of motility disorders, e.g. dysphagia
6. Presence of major oesophageal dysmotility on manometry, e.g. achalasia, diffuse spasm, aperistalsis (greater than 80% swallows)
7. Significant co-morbidity requiring ongoing treatment or investigation
8. Physical, neurological or psychiatric conditions preventing repeated visits to hospital or compliance with study procedures (e.g. physical impairment/reduced mobility)
9. Pregnancy or lactation at the time of enrolment

Date of first enrolment

01/06/2010

Date of final enrolment

01/06/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Oesophageal Laboratory

London

United Kingdom

SE1 7EH

Sponsor information**Organisation**

Guy's and St Thomas' NHS Foundation Trust (UK)

Sponsor details

Research & Development Department
3rd Floor Conybeare House
St Thomas Street
London
England
United Kingdom
SE2 9RT

Sponsor type

Hospital/treatment centre

Website

<http://www.guysandstthomas.nhs.uk/>

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Government

Funder Name

Guy's and St Thomas' Hospital NHS Trust (UK) - covering the costs of the procedure and indemnity

Funder Name

Reckitt Benckiser (UK) - covering the cost of Gaviscon Advance® product

Funder Name

Guys' and St Thomas' Charity HPB Fund 872 (UK) - covered additional costs of running the trial and Milk of Magnesia product

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	01/06/2013		Yes	No