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Gaviscon Advance® versus milk of magnesia pH-impedance study

Submission date	Recruitment status	[_] Prospectively registered
18/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/08/2014	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
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 The study terminates when the catheter is withdrawn.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