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Gaviscon double action versus placebo study using the BRAVO System

Submission date 22/07/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/08/2010	**Overall study status** Completed	
Last Edited 19/04/2017	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Terry Wong

Contact details
Department of Gastroenterology
College House
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GA1001

Study information

Scientific Title
A randomised, double-blind placebo-controlled study in patients with reflux symptoms to assess suppression of gastro-oesophageal reflux by 'Gaviscon Double Action peppermint liquid' using the BRAVO System

Study objectives
The primary hypothesis is that in patients presenting with symptoms suggesive of reflux disease, reflux suppression of Gaviscon Double Action (a liquid product containing antacid and alginate components which treats heartburn and indigestion) is effective at reflux suppression and symptom reduction compared to a closely matched placebo or no treatment.

This is a pilot, mechanistic study that is designed primarily to test the mechanism of the effect (i. e. reflux suppression) with clinical efficacy (i.e. symptom suppression) as a secondary outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled double-blind parallel-group study

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Gastroesophageal reflux disease

Interventions
A wireless pH monitoring capsule will be attached into the oesophagus endoscopically as per routine. Patients are then sent away with a wireless receiver to collect information regarding oesophageal acid exposure, and a diary card to record all symptoms and events for two consecutive sets of 48 hours. Gaviscon Double Action Peppermint liquid or a closely matched placebo will be self-administered four times a day after meals and before bed for two days and

no treatment will be administered on the other two days. The sequence of these periods will follow consecutively and will be determined by prior randomisation. For all subjects, acid reflux events and symptoms will be recorded over all four days, after which the treatment /investigation period for that patient will terminate.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gaviscon Double Action peppermint liquid

Primary outcome measure
The number of acid reflux events during 48 hour Gaviscon Double Action or matched placebo study period compared to the 48 hour 'no treatment' study period

Secondary outcome measures
1. The combined number of acid reflux events and weakly acid reflux events during the Gaviscon Double Action or matched placebo study period compared to the 48 hour 'no treatment' study period. A weakly acid reflux event is defined as any fall in pH of more than 2 pH units in an interval of less than 1 minute which is maintained for a duration of at least 12 seconds.
2. Oesophageal acid exposure (percentage of time with pH less than pH 4) during the Gaviscon Double Action or matched placebo study period compared to the 48 hour 'no treatment' study period
3. Categorical presence/absence of pepsin in expectorated saliva acquired 2 hours after the main evening meal on each test day at detection threshold 16 ng/ml of 'pepsin lateral flow test'
4. Pepsin concentration in expectorated saliva acquired 2 hours after the main evening meal on each test day assessed by ELISA
5. Severity and duration of symptoms/time until symptomatic relief, documented by study subjects in the patient diary
6. The number of typical reflux symptoms (heartburn, acid regurgitation) documented by study participants on data logger/receiver and diary card during the Gaviscon Double Action or matched placebo study period compared to the 48 hour 'no treatment' study period
7. The number of typical reflux symptoms (heartburn, acid regurgitation) in the postprandial and night-time periods in the 2 hour period after self-administration of the test product during the Gaviscon Double Action or matched placebo study period compared to the 48 hour 'no treatment' study period

Overall study start date
01/12/2010

Completion date
01/10/2011

Eligibility

Key inclusion criteria

1. Aged greater than or equal to 18 years and less than or equal to 70 years
2. Male and female patients
3. Primary diagnosis is those with self-rated at least moderate heartburn or acid regurgitation within 60 minutes following ingestion of a refluxogenic meal on at least three occasions a week at the screening visit
4. Agreement to withhold acid suppressant PPI and H2 receptor blocking medications and other medications that affect gastro-intestinal function for 6 days and 3 days respectively prior to the test and during 4 days of monitoring
5. Agreement to withhold antacids or alginate preparations, except those administered as part of study procedures for 1 day prior to the test and during 4 days of monitoring
6. Patients who gave written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 (20 in each arm)

Key exclusion criteria
1. Those with prominent gastrointestinal symptoms or disease other than reflux (including atypical symptoms, e.g. cough, sore throat, belching, nausea)
2. Those with difficulty swallowing (dysphagia), gastrointestinal bleeding, weight loss (greater than 5% body weight) or other alarm symptoms suggestive of neoplastic or severe inflammatory disease within the last 12 months
3. Those with a history or symptoms suggestive of Zollinger-Ellison syndrome, gastric carcinoma, previous or current peptic ulcer disease, pernicious anaemia, Barrett's oesophagus or systemic sclerosis
4. Those with a history of upper GI surgery or endoscopic interventions such as oesophageal dilatations or mucosal resection
5. Those with known hypophosphataemia or phenylketonuria
6. Those with severe constipation or history of colonic stenosis
7. Those with major oesophageal dysmotility on manometry, e.g. achalasia
8. Those with severe reflux oesophagitis on endoscopy (LA grade III - IV) or Barrett's oesophagus on endoscopy
9. Those with significant co-morbidity requiring ongoing treatment or investigation
10. Those with haematological disorders, bleeding tendency, recurrent nose bleeds or treatment with anti-coagulants
11. Those with physical, neurological or psychiatric conditions preventing repeated visits to hospital or compliance with study procedures (e.g. physical impairment/reduced mobility)
12. Woman of childbearing potential, who are pregnant or lactating, seeking pregnancy or failing to take adequate contraceptive precautions, (i.e. sexual an oral or injectable contraceptive, an

approved hormonal implant or topical patch, an intrauterine device, abstinence [should the subject become sexually active, she must agree to use a double barrier method]). A woman of childbearing potential is defined as any female who has not undergone the menopause or has not had an hysterectomy or surgical sterilisation procedure, e.g. bilateral tubal ligation, bilateral ovariectomy (oophorectomy).
13. Those that do not withhold acid-suppressant PPI and H2 receptor blocking medications for 6 days and 3 days respectively prior to the test and during 4 days of monitoring
14. Those that do not withhold antacid or alginate medications for 1 days prior to the test and during 4 days of monitoring (5 days in total)
15. Those who have any previous history of allergy or known intolerance to any of the study drugs or the following formulation constituents: Gaviscon® liquid: sodium alginate, sodium bicarbonate, calcium carbonate, carbomer, methyl parahydroxybenzoate, propyl parahydroxybenzoate, saccharin sodium, peppermint flavour, sodium hydroxide, Placebo: hydrogenated glucose syrup, peppermint flavour, potassium sorbate, methyl paraben, xanthan gum r80, propyl paraben, citric acid
16. Failure to accept or to comply with standard requirements for activity and diet during pH testing
17. Those unable in the opinion of the Investigator to comply fully with the study requirements

Date of first enrolment
01/12/2010

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Reckitt Benckiser Healthcare (UK)

Sponsor details
Dansom Lane
Hull

United Kingdom
HU8 7DS

Sponsor type
Industry

Website
http://www.rb.com

ROR
https://ror.org/01g87hr29

Funder(s)

Funder type
Industry

Funder Name
Reckitt Benckiser Healthcare (UK)

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