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A phase III multicentre, randomised, double blind, placebo controlled, parallel group study of renzapride in women with constipation predominant Irritable Bowel Syndrome (IBS)

Submission date
22/12/2005

Registration date
24/01/2006

Last Edited
28/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anthony Lembo

Contact details
Beth Israel Deaconess Medical Centre
Boston
United States of America
MA 02215

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00268879

Protocol serial number
ATL1251/038/CL

Study information

Scientific Title
Clinical trial: renzapride treatment of women with irritable bowel syndrome and constipation – a doubleblind, randomized, placebocontrolled, study

Study objectives
To investigate whether renzapride will help alleviate the symptoms associated with constipation predominant irritable bowel syndrome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Copernicus Group Institutional Review Board (IRB) on the 30/09/2005 (ref QUI1-05-131).

Study design
Randomised, double blind, placebo controlled, parallel group

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Constipation predominant irritable bowel syndrome

Interventions
Oral (capsules), 4 mg renzapride once daily (OD), 2 mg renzapride twice daily (BD) or placebo, taken for 12 weeks with a 4-week safety follow-up period.

N.B. In the USA only, patients who completed the full 12 weeks of treatment were invited to enrol in a follow-on, open label, long-term safety study (ATL1251/052/CL) in which all patients took oral (capsules), 4 mg renzapride OD for up to 12 months; this study is ongoing and is due to report during 1H 2009.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Renzapride

Primary outcome(s)
Number of months a patient is a responder for overall relief of IBS symptoms

Key secondary outcome(s))
Number of months a patient is a responder for relief of abdominal pain/discomfort, bowel problems and bloating/abdominal distention

Completion date
31/01/2007

Eligibility

Key inclusion criteria
1. Females, aged 18-65, with constipation predominant IBS as defined by the Rome II criteria
2. Colonoscopy or sigmoidoscopy in the previous 5 years showing no significant disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
Female

Key exclusion criteria
1. Patients who have predominant diarrhoea or alternating symptomatic IBS
2. Other gastrointestinal diseases that affect bowel transit

Date of first enrolment
05/12/2005

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
Argentina

Canada

Chile

Colombia

United States of America

Study participating centre
Beth Israel Deaconess Medical Centre
Boston
United States of America
MA 02215

Sponsor information

Organisation
Alizyme (UK)

Funder(s)

Funder type
Industry

Funder Name
Alizyme (UK)

Results and Publications

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	01/02/2010	28/01/2019	Yes	No