

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/01/2019	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

Contact name
Dr Anthony Lembo

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00268879

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Number of months a patient is a responder for overall relief of IBS symptoms

Secondary outcome measures

Number of months a patient is a responder for relief of abdominal pain/discomfort, bowel problems and bloating/abdominal distention

Overall study start date

05/12/2005

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Female

Target number of participants

1700 (This trial is no longer recruiting, and the completion date of this trial is estimated to be sometime during 1Q 2008).

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)

Sponsor details

Granta Park

Great Abington

Cambridge

United Kingdom

CB1 6GX

+44 (0)1223 896000

Medical.Information@alizyme.co.uk

Sponsor type

Industry

Website

<http://www.alizyme.com>

Funder(s)

Funder type

Industry

Funder Name

Alizyme (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010	28/01/2019	Yes	No