

Assessment of spasmodigestin tablets in treatment of cases of irritable stomach syndrome

Submission date 01/09/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/09/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/09/2022	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Functional dyspepsia (FD; recurring signs and symptoms of indigestion that have no obvious cause) is one of the most common functional disorders, with a prevalence of 10–30% worldwide. Dyspeptic symptoms are common and cause considerable direct effects (visits to the doctor, medications, etc.) and particularly indirect costs (time off work).

Who can participate?

Patients aged 18 - 60 years with functional dyspepsia

What does the study involve?

A total of 251 patients were enrolled for a Prospective, Open Label, Interventional Phase IV study and 199 patients completed the follow-up visit. Each eligible patient was dispensed Spasmodigestin® Enteric Coated tablets taken as 2 tablets three times daily for 10 days. The aim of the study was to evaluate Efficacy and Safety of Spasmodigestin® Enteric Coated tablets in Patients with Functional Dyspepsia. Efficacy was evaluated by several outcomes including the evaluation of the overall change in dyspeptic symptoms as a score of (0 to 3) for each symptom. For further assessment of the efficacy, patients were asked to self-rate the intensity of each dyspeptic symptom at baseline visit and at the end of the study duration. Moreover, the proportion of responders to treatment (patients having at least a 50% decrease of Dyspeptic symptoms) was evaluated.

The impact of dyspeptic symptoms on patients' quality of life represented as five areas (tension, interference with daily activities, eating/drinking, knowledge/control, and work/study) was assessed at the end of treatment duration, by Nepean Dyspepsia Index.

What are the possible benefits and risks of participating?

None of the study patients reported any serious adverse events throughout treatment period but, only one patient (0.5%) reported mild diarrhoea as an adverse event. Results revealed that Spasmodigestin Enteric Coated tablet is safe and effective in the treatment of the symptoms of Functional Dyspepsia.

Where is the study run from?
TCD MENA (Egypt)

When is the study starting and how long is it expected to run for?
March 2015 to June 2019

Who is funding the study?
Pharco pharmaceutical company (Egypt)

Who is the main contact?
Dr Walaa Nasr, walaa.nasr@tcdmena.com

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

PHAR_SPASMO_001

Study information

Scientific Title

Evaluation of efficacy and safety of Spasmodigestin® enteric coated tablets in patients with functional dyspepsia: a prospective, open label, interventional phase IV study

Study objectives

Spasmodigestin® enteric coated tablets had high efficacy in the treatment of the studied patients with functional dyspepsia. Spasmodigestin® tablets showed a favorable safety and tolerability profile in the studied population. so accordingly, the treatment of patients with functional dyspepsia with Spasmodigestin® following the approved SmPC is safe and effective in symptomatic relief and improvement of QoL parameters.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 29/03/2016, Research Ethics Committee of Ministry of health & population (3 magles elshaab street, floor 7, Cairo, 11516, Egypt; +20 227950678, rhd@mohp.gov.eg), ref: IRB000687
2. Approved 08/03/2016, Research ethics committee, medical research institute, Alexandria university (165 horreya Avenue, Hadara, Alexandria, Egypt; +2034282331; ethics.committee.human@alexu.edu.eg), ref: none provided
3. Approved 26/11/2015, Ethics committee of faculty of medicine, Alexandria university (17 champollion street, el messalah, Alexandria, Egypt; +201287740750; alexmedethics@yahoo.com), ref: 00007555
4. Approved 04/01/2016, Ethics committee of faculty of medicine, ain shams university (38 Abbassia, Next to the Al-Nour Mosque, Cairo, Egypt; +20226857539; alaazorkany@yahoo.com), ref: FWA 00017585

Study design

Prospective multi-centre interventional open-label phase IV study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

GP practice

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

Functional dyspepsia

Interventions

This was a prospective, open label, interventional, phase IV, multi-centre study. Patients were administered Spasmodigestin® oral tablets according to the approved summary of product characteristics (SmPC). Each eligible patient was dispensed 60 tablets of Spasmodigestin® at baseline visit in the form of two Spasmodigestin® boxes, each box contains 3 strips and each strip contains 10 enteric coated tablets. The dose was 2 tablets three times daily (immediately before each meal) for 10 days as per the investigator's judgment.

The patients' compliance and daily doses were recorded in patients self-administered diaries. Patients attended a total of three visits including; screening visit (day -7), baseline visit (day 0) and a follow-up visit (day 10).

Patients were given diaries to record dyspeptic symptoms, intensity of dyspeptic symptoms and Napean Dyspepsia Index. Patients were also asked to record the daily total amount of tablets taken. In addition, concomitant medications were recorded.

Intervention Type

Drug

Phase

Phase III/IV

Drug/device/biological/vaccine name(s)

Spasmodigestin® Enteric Coated tablets (Dicyclomine, Papain, Sanzyme 3500, Simethicone and Sodium Dehydrocholate.)

Primary outcome measure

1. Efficacy measured using dyspeptic symptoms (fullness, flatulence, early satiety, nausea, vomiting, epigastric pain) used an index for the global response over treatment period (10 days)
2. Safety measured using serious adverse events using patient records (10 days duration)

Secondary outcome measures

1. Patient's self-rating of the intensity of each dyspeptic symptoms using a four-point Likert scale (10 days duration)
2. Sum score of differences between baseline and improvement of health-related quality of life using short form Nepean dyspepsia index over 10 days
3. Number of responders (50% decrease of dyspeptic symptoms) measured using the patient's self-rating of intensity four-point Likert scale and Short Form Nepean Dyspepsia Index (SF-NDI) at baseline and at 10 days after treatment
4. Total number of pills consumed measured using patients self- administrate diaries during 10 days.
5. Number of patients with on-treatment adverse events measured by asking the subject after 10 days of treatment.
6. The number of patients discontinued due to adverse events measured using patients self-administrate diaries and by asking the subject at 10 days of treatment
7. The main reasons for treatment failure and delayed response measured using patients self-rating of intensity four-point Likert scale and Short Form Nepean Dyspepsia Index (SF-NDI) at baseline and at 10 days after treatment.

Overall study start date

24/03/2015

Completion date

30/06/2019

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years and < 60 years
2. Patients with functional dyspepsia who are defined as having upper abdominal pain or discomfort with one or more of the following symptoms: early satiety, postprandial fullness, bloating and nausea with the absence of GIT clinically significant findings.
3. Patients with acute onset of dyspeptic symptoms for less than 6 months and able to provide written informed consent.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

251

Total final enrolment

Key exclusion criteria

1. Patients with chronic onset of dyspeptic symptoms for more than 6 months
2. Patients with inflammatory bowel disease (IBS), chronic calculous cholecystitis, lactose intolerance, psychiatric disorder requiring medication, major hepatic, renal or haematological diseases.
3. Patients with history of malignancy, laparoscopic or open abdominal surgery within the previous 6 months
4. Patients with history of the following diseases within the previous 6 months; peptic ulcer disease, GI bleeding, gastroesophageal reflux disease, intestinal stenosis or obstruction, infectious diarrhoea, or pancreatitis Also, patients with Unexplained iron deficiency anaemia, unintentional weight loss, dysphagia or persistent vomiting at time of study.
5. Patients with known allergy to the study drug. or taking concomitant medication acting on or influencing the gastrointestinal system (e.g., proton-pump inhibitors, H2 blockers, cholagogues, prokinetic agents, non-steroidal anti-inflammatory drugs, or theophylline).
6. Patients on antidepressant or anxiolytic treatment.
7. Pregnant or lactating female patients.
8. Female patients of childbearing age not using contraception.

Date of first enrolment

12/12/2017

Date of final enrolment

18/06/2019

Locations**Countries of recruitment**

Egypt

Study participating centre

Medical research institute, Alexandria university

165 AboQir street

El Horreya road

elhadara bahary

Alexandria

Egypt

21561

Study participating centre

Faculty of medicine, Alexandria University

17 Champion street

Azarita

Alexandria

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21568

Study participating centre
Faculty of medicine, Ain Shams University
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Sponsor type

Research organisation

Website

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Organisation

Pharco pharmaceutical company

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Sponsor type

Industry

Website

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Funder(s)**Funder type**

Industry

Funder Name

Pharco pharmaceutical company

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/12/2022

Individual participant data (IPD) sharing plan

Available on request

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IPD sharing plan summary

Available on request