ISRCTN10744532 https://doi.org/10.1186/ISRCTN10744532

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

Submission date
01/09/2022

Recruitment status
No longer recruiting

Registration date
05/09/2022

Overall study status
Completed

Last Edited
05/09/2022

Condition category
Digestive System

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

Contact name
Dr Walaa Nasr Elghitany

Contact details
112 B Ammar ben yaseer street
Heliopolis
Cairo
Egypt
11736
+20 1118589490
walaa.nasr@tcdmena.com

Type(s)
Scientific

Contact name
Dr Walaa Nasr Elghitany

Contact details
112 B, Ammar ibn yasser
Heliopolis
Cairo
Egypt
11736
+20 1118589490
walaa.nasr@tcdmena.com

Type(s)
Principal investigator

Contact name
Dr Walaa Nasr

Contact details

112 B, Ammar ibn Yasser
Heliopolis
Cairo
Egypt
11736
+20 1118589490
walaa.nasr@tcdmena.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Functional dyspepsia

Interventions
This was a prospective, open label, interventional, phase IV, multi-centre study. Patients were administrated 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- administrate dairies. Patients attended a total of three visits including; screening visit (day -7), baseline visit (day 0) and a follow-up visit (day 10).
Patient were given diaries to record dyspeptic symptoms, intensity of dyspeptic symptoms and Nepean 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(s)
1. Efficacy measured using dyspeptic symptoms (fullness, flatulance, 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)

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
251

Key exclusion criteria
1. Patients with chronic onset of dyspeptic symptoms for more than 6 months
2. Patients with inflammatory bowel disease (IBS), chronic calcular 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 inti-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 Champlion street
Azarita
Alexandria
Egypt
21568

Study participating centre
Faculty of medicine, Ain Shams University
Ramsis street
elabbasyia
Cairo
Egypt
11591

Sponsor information

Organisation
TCD MENA

Organisation
Pharco pharmaceutical company

Funder(s)

Funder type
Industry

Funder Name
Pharco pharmaceutical company

Results and Publications

Individual participant data (IPD) sharing plan
Available on request
walaa.nasr@tcdmena.com

IPD sharing plan summary
Available on request