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Analysis of the effects of GERDOFF tablets in patients with gastric reflux who do not respond to other drugs (alginates)

Submission date
15/12/2017

Recruitment status
No longer recruiting

Registration date
19/12/2017

Overall study status
Completed

Last Edited
31/07/2020

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Gastroesophageal reflux (English acronym GERD, Gastro-Oesophageal Reflux Disease) is caused by a functional defect in the oesophagus and is characterized by the reflux of stomach contents and of gases produced in the intestine into the oesophagus, generating a reflux of acid material. The GERD symptoms include burning chest, acid and alkaline regurgitation from lying down, stomach cramps, and difficulty in swallowing. Some people have gastric reflux which is not cured by other drugs. In this study we evaluate if GERDOFF tablets can be helpful to reduce gastric reflux and heartburn.

Who can participate?
Adults aged 18 and older who have gastric reflux.

What does the study involve?
All participants receive GERDOFF tablets for two weeks after meals and before bedtime. Participants are followed up to see if they

What are the possible benefits and risks of participating?
The possible benefits are symptoms alleviation and improvement of quality of life; the main potential risk is that the device does not work. Side effects to treatement are not expected since the product is already commercially available.

Where is the study run from?
The University of Modena (Italy) and the Hospital of Cernusco sul Naviglio (Italy) are the centres taking part in this trial. The University of Modena is the lead centre.

When is study starting and how long is it expected to run for?
The study started in 2014 and is currently completed.

How long will the trial be recruiting participants for?
SOFAR Spa (Italy)

Who is the main contact?
Dr Alberto Merighi merighi.alberto@policlinico.mo.it

Contact information

Type(s)
Scientific

Contact name
Dr Alberto Merighi

Contact details
via del Pozzo 71
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41124

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RE-GERD 14

Study information

Scientific Title
Exploratory, post-market, open-label clinical investigation to evaluate the effect of the medical device, GERDOFF® melt-in-mouth tablets, in patients with GERD and with reduced effect or ineffectiveness of alginates treatment.

Acronym
GERDOFF® efficacy in patients with GERD

Study objectives
The purpose of this exploratory clinical investigation is to evaluate the effect of GERDOFF® in reducing the number of 'heartburn' episodes, GERD symptom manifestation, per week, after 14 days of treatment, by assessing the number of days with the symptom "heartburn" over the last week of treatment compared to baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Azienda Ospedaliero-Universitaria Policlinico di Modena (University Hospital of Modena), 08/10/2014, Substantial Amendment version 2.0 was acknowledged by EC on 04/06/2015, ref: 137.14
2. For Substantial Amendment version 2.0 by Comitato Etico Interaziendale Area A Milano (Ethics Commitee Intercompany Area A Milan), 24/06/2015

Study design
Post-marketing exploratory open-label two sites clinical study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
All patients are trained to take 4 melt-in -mouth tablets containing high molecular weight hyaluronic acid, aluminum hydroxide, and chondroitin sulphate (GERDOFF® 1100 mg; SOFAR S.p. A., Trezzano Rosa, Milan, Italy) after meals and before bedtime, for 14 days.

Participants are followed up to see if there is a reduction in the number of heartburn episodes per week and the frequency of their symptoms.

Intervention Type
Other

Primary outcome measure
Reduction in the number of heartburn episodes per week is measured using patient diaries at baseline, day 7 and day 14.

Secondary outcome measures
1. Frequency of GERD- related symptoms are measured using patient diaries and the GIS Gerd impact scale questionnaire at baseline, day 7 and 14
2. Patient satisfaction is measured using GIS Gerd impact scale questionnaire at baseline, day 7 and day 14
3. Number of days without symptoms are measured using patient diaries at baseline, day 7 and day 14

4. Patient’s compliance to the therapy is measured using patient diaries at baseline, day 7 and day 14

Overall study start date
30/05/2014

Completion date
20/06/2017

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Having symptoms associated to diagnosis of GERD, performed on clinical basis with the presence of following symptoms
2.1. Heartburn and/or regurgitation, diurnal and/or nocturnal, of moderate intensity, at least twice a week, for at least two weeks, disturbing the patient during normal activities and/or in the recovery of night-time sleep, whether or not accompanied by other symptoms
3. Having a medical report of EGDS performed within 3 months prior to the study start, excluding other diseases in the upperpart of the digestive system (e.g. erosion/ulcer gastric or duodenal)
4. Responding to PPI treatment during the 6 months prior to the study start
5. Having a disease not controlled by alginate treatment, taken on the basis of the dosage recommendations given in the leaflet for at least 2 weeks prior to study initiation
6. Being able to understand and comply with the study procedures
7. Being able to provide a written informed consent to participate into the study
8. Being able to provide a consent to the processing of personal data related to the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 patients

Total final enrolment
40

Key exclusion criteria
1. Known esophagitis caused by infection or by acid or alkaline substances
2. Treatment for eradication of Helicobacter Pylori (HP) in the 30 days prior to informed consent signature

3. Concomitant PPI therapy, if not already in use in the 2 weeks prior to V0
4. Expected alginates intake during the study
5. Patients, who planned to use during the course of the study anti-acids, prokinetics, anti-H2, or other pharmaceutical products and/or over-the-counter products and/or medical devices indicated for the treatment of GERD, will not be included
6. History of Zollinger-Ellison syndrome, hiatal hernia and Barrett's oesophagus
7. Known diabetes
8. Inability of the patient to adequately describe his/ her disorders
9. Unauthorized consent to the processing of personal data
10. Planned or known pregnancy
11. Breastfeeding
12. Participation in other clinical trials/investigations with drugs or experimental products within 3 months prior to enrolment

Date of first enrolment
18/12/2014

Date of final enrolment
30/01/2017

Locations

Countries of recruitment
Italy

Study participating centre
Azienda Ospedaliero-Universitaria
Modena
Italy
41124

Study participating centre
Presidio Ospedaliero
Cernusco sul Naviglio
Italy
20063

Sponsor information

Organisation
Sofar Spa

Sponsor details

Via Firenze, 40
Trezzano Rosa
Italy
20060

Sponsor type
Industry

Website
http://www.sofarfarm.it/

ROR
https://ror.org/04f3x2j17

Funder(s)

Funder type
Industry

Funder Name
Sofar Spa

Results and Publications

Publication and dissemination plan
An article on this study is already ready to be submitted to scientific journals. The protocol and the statistical analysis plan have not been published online. The study was completed in 2017.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Alberto Merighi merighi.alberto@policlinico.mo.it. Data that will be available will be vital the responses of GIS questionnaire, for 5 years from publication. Data will be accessible for anyone who wish to perform individual patient data metanalysis. Proposals should be directed to dr Merighi Alberto. Data will be anonimyzed before sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2020	31/07/2020	Yes	No