Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of cetrizine on symptoms and histologic changes (count of mast cells) of gastric mucosa in patients with proton pump inhibitor resistant functional dyspepsia.

Protocol summary

Summary

The study evaluates the effects of cetrizine on symptoms and histological changes (count of mast cells) of gastric mucosa in patients with proton pump inhibitor resistant functional dyspepsia. The patients with the diagnosis of functional dyspepsia who had undergone esophagogastroduodenoscopy and biopsy of antrum and body will be enrolled in the study. A sample volume of 30 patients is considered being a pilot study. The cases with other medical conditions or pathologic changes explaining the symptom of dyspepsia or a positive H.pylori on RUT or biopsy will be excluded. The patients fill a check list evaluating the severity of symptoms and ROME III questionnaire. The specimen will be stained with H & E and (if H. pylori infection is not found) toluidine blue. The eligible patients are treated with cetrizine 10 mg/qhs with ranitidine 150 mg/bid for 6 weeks. At the end of the treatment period, another checklist about severity of the symptoms and drug side effects will be introduced and a second endoscopy with biopsy of antrum and body with the same histological evaluation will be performed. Change in the mast cell count and its correlation with symptoms will be assessed as primary aims of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121211738N1**
Registration date: **2013-01-19, 1391/10/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-19, 1391/10/30

Registrant information

Name
Kurosh Masnadi Shirazi
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1334 7554
Email address
masnadik@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of cetrizine on symptoms and histologic changes (count of mast cells) of gastric mucosa in patients with proton pump inhibitor resistant functional dyspepsia.

Public title

Effect of cetrizine on functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria 1. Fulfillment of ROMEIII criteria 2. Absence of any underlying medical disorder 3. Normal

routine lab tests hepatoblliary ultrasound 4. Unrevealing esophagogastroduodenoscopy 5. Negative result of H. pylori tests Exclusion criteria Diagnosis anothert underlying cause for dyspepsia, incompliance (more than 10 % missed doses of medication), positive H. pylori tests, History of taking antihistaminics in passed 3 minthes.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Before/after study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Daneshgah street.

City
Tabriz

Postal code

Approval date
2012-11-27, 1391/09/07

Ethics committee reference number
5/4/7938

Health conditions studied

1

Description of health condition studied
Functional Dyspepsia

ICD-10 code
K31

ICD-10 code description
functional disorders of stomach

Primary outcomes

1

Description
Mast cell count in histologic study of gastric mucosa

Timepoint
Before and after a course of treatment

Method of measurement
Mean of mast cell count in high power fields of gastric mucosa stained with toluidine blue

Secondary outcomes

1

Description
Change in severity of symptoms

Timepoint
Before and after the treatment course

Method of measurement
A checklist of multiple choice question

Intervention groups

1

Description
cetrizine 10 mg at bedtimes for 6 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinics of Sheikhorrais and Emamreza hospital

Full name of responsible person

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Kurosh Masnadi shirazi MD

Street address
Tabriz University of Medical Sciences, Golgasht ave.

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Sadrkabir
Position
Fellow of Gastroenterology and Hepatology
Other areas of specialty/work
Street address
Emamreza hospital,Endoscopy ward, Golgasht ave.
City
Tabriz
Postal code
Phone
+98 41 1334 7289
Fax
Email
sadrkabir@gmail.com , sadrkabir@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Sadrkabir
Position
Fellow of Gastroenterology and Hepatology
Other areas of specialty/work
Street address
Emamreza hospital, Golgasht ave.
City
Tabriz
Postal code
00984113347289
Phone
00894113347289
Fax
Email
sadrkabir@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Sadrkabir
Position
Fellow of Gastroenterology and Hepatology
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty