

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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 hepatobiliary ultrasound 4. Unrevealing esophagogastroduodenoscopy 5. Negative result of H. pylori tests Exclusion criteria Diagnosis another underlying cause for dyspepsia, in compliance (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

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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

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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