

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Study of the effect of medications used to treat *Helicobacter pylori* infection on quality of life in chronic idiopathic urticaria

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of medications used to treat *Helicobacter pylori* infection on quality of life in chronic idiopathic urticaria . This study is a single blind clinical trial. The study population will included all patients with chronic urticaria (CIU)with *Helicobacter pylori* infection refer to the Mohammad Kermanshahi hospital of Kermanshah city. A total of 60 persons will be selected in available method and by permuted-block randomization will be assigned to two experimental and control groups. At baseline Quality of Life Questionnaire (CU-Q2OL) will be provided for both experimental and control groups,then in experimental group addition to the routine treatment of chronic urticaria, drug treatment OMC (Omeprazole, Metronidazole, Clarithromycin) will be prescribed for *Helicobacter pylori* infection for 2 weeks and the control group will receive usual treatment of chronic urticaria and placebo. In order to medication control, the patient during treatment for 2 weeks, at the end of the first week and the end of the second week refer physician to control. After the treatment course Ag stool exam test will be taken again to determine the effect of drugs on reducing *Helicobacter pylori* infection. A month after the start of the study and two months after treatment quality of life questionnaire will be provided to both groups again. Inclusion criteria: Patients with chronic urticaria for at least 6 weeks. Exclusion criteria: Pregnant and lactating women; people under 20 and over 40 years old; patients with severe Angioedema

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082114333N56**

Registration date: **2016-08-27, 1395/06/06**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2016-08-27, 1395/06/06

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Not enough for processing

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-09-10, 1395/06/20

Expected recruitment end date

2006-11-11, 1385/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of medications used to treat *Helicobacter pylori* infection on quality of life in chronic idiopathic urticaria

Public title

Effectiveness of medications used to treat *Helicobacter pylori* infection on quality of life in chronic idiopathic

urticaria patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with chronic urticaria for at least 6 weeks; Normal laboratory data and physical examination to detect the possible causes of chronic urticaria. Exclusion criteria: Pregnant and lactating women; people under 20 and over 40 years old; patients with severe Angioedema; Chronic alcoholics and patients with a history of recent use of proton pump inhibitors drugs, antibiotics and bismuth or non steroidal anti-inflammatory drugs or ACE

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
permuted-block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2016-03-02, 1394/12/12

Ethics committee reference number
kums.rec.1394.490

Health conditions studied

1

Description of health condition studied

Chronic urticaria

ICD-10 code

L50

ICD-10 code description

Urticaria

Primary outcomes

1

Description

Quality of life

Timepoint

Baseline, a month and two months after intervention

Method of measurement

Quality of Life Questionnaire (CU-Q2OL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group addition to the routine treatment of chronic urticaria, will receive drug treatment OMC (Omeprazole, Metronidazole, Clarithromycin) for Helicobacter pylori infection for 2 weeks.

Category

Treatment - Drugs

2

Description

The control group will receive usual treatment of chronic urticaria and placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Maryam Taburak

Street address

Mohammad Kermanshahi Hospital, Crossroads of shirkhorshid

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Seyed Hamid Mortezaavih

Position

Immunologists

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Maryam Taburak

Position

Student of Medical

Other areas of specialty/work

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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