Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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Iran (Islamic Republic of)
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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 40years 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
Utricaria

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 received 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 Mortezavih
Position
Immunologists
Other areas of specialty/work
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Person responsible for updating data

Contact
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Kermanshah University of Medical Sciences
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Maryam Taburak
Position
Student of Medical
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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