Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effects of Cetirizine and Desloratadine on the symptoms of chronic spontaneous urticarial and quality of life

Protocol summary

Study aim

Determining the difference in the effectiveness of Cetirizine and Desloratadine on quality of life and clinical symptoms in CSU patients (resistant to AntiH2) - Comparison of the effects of two drugs in reducing the symptoms of CSU patients -Comparison of the effects of two drugs, on the quality of life of CSU patients

Design

A clinical trial with the control group, with parallel groups, randomized, on 180 patients. Blocked randomization. Cards that identify the intervention and control group are prepared using the Stata software and 4, 6, and 8 size blocks for concealment.

Settings and conduct

This study aims to compare two drugs, Cetirizine and Desloratadine, on patients referred to the Allergy and Immunology Department of Ghaem Mashhad Hospital. After obtaining informed consent, the characteristics of the patients are measured through a questionnaire at the beginning and two weeks later. During this, patients in two separate groups are treated with cetirizine and Desloratadine (4 times the standard dose).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 18 to 65 years old 2. History of spontaneous chronic urticaria for a period of at least six weeks during the last three months 3. Failure to respond to usual doses of second-generation antihistamines 4. Lack of disease control based on the score of the UCT questionnaire Exclusion criteria: 1. Pregnancy 3. History of other types of urticaria and hereditary angioedema.

Intervention groups

Intervention group 1: 90 eligible patients are treated with 4 times the standard therapeutic dose of cetirizine for 2 weeks. Intervention group 2: 90 eligible patients are treated with 4 times the standard therapeutic dose of desloratadine for 2 weeks.

Main outcome variables

Changes in quality of life, pruritus and urticaria based on a questionnaire (CU-QoL) and UCT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211219053449N1**
Registration date: **2022-10-16, 1401/07/24**
Registration timing: **prospective**

Last update: **2022-10-16, 1401/07/24**
Update count: **0**

Registration date

2022-10-16, 1401/07/24

Registrant information

Name

Elahe Moradzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 0884

Email address

moradzadehe991@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-22, 1402/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Cetirizine and Desloratadine on the symptoms of chronic spontaneous urticarial and quality of life

Public title

Comparison of the effects of Cetirizine and Desloratadine on the symptoms of chronic spontaneous urticarial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The purpose of the study will be explained to all patients and written informed consent will be obtained. CSU patients with a history of chronic spontaneous urticaria for at least six weeks during the last three months who did not respond to standard doses of second-generation antihistamines the illness was not controlled according to the disease questionnaire.

Exclusion criteria:

Pregnancy Drug-induced urticaria Vasculitis urticaria Hereditary angioedema Colitis urticaria Physical urticaria cold urticaria

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization. Using software and 4, 6 and 8 size blocks for hiding, the cards that identify the intervention and control group are prepared and then placed in opaque envelopes and the envelopes are arranged and numbered according to the sequence produced by the software and the patients are arranged accordingly. Admission (envelope number one for the first patient and two for the second, etc.) are assigned to the intervention or comparison group according to the card in the envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences

Street address

university street

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.163

Health conditions studied

1

Description of health condition studied

Chronic urticaria

ICD-10 code

L50

ICD-10 code description

Urticaria

Primary outcomes

1

Description

UCT questionnaire score: assessment of pruritus and urticaria symptoms

Timepoint

before and after 14 days of taking the drug

Method of measurement

UCT questionnaire

2

Description

CU-QoL questionnaire: assessment of quality of life

Timepoint

At the beginning of the study and 2 weeks after taking the drug

Method of measurement

Chronic Urticaria-Quality of Life Questionnaire (CU-QoL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: prescription of cetirizine tablets

from Abidi pharmaceutical company in 4 times the standard dose for 2 weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: Administration of Desloratadine tablets from Abidi pharmaceutical company in 4 times the standard dose for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy and Immunology Department of Ghaem Hospital

Full name of responsible person

Maryam Khoshkhui

Street address

Ahmadabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 915 306 4631

Email

moradzadehe991@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

majid Ghayour mobarhan

Street address

daneshgah str.

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Dr. Abidi Pharmaceuticals

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Khoshkhui

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Allergy and clinical immunology

Street address

daneshgah str.

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3840 0000

Email

KhoshkhuiM@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

maryam Khoshkhui

Position

assiatant proff.

Latest degree

Subspecialist

Other areas of specialty/work

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Postal code

9138813944

Phone

+98 51 3840 0000

Email

KhoshkhuiM@mums.ac.i

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

maryam Khoshkhui

Position

assistant proff.

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available