

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the therapeutic effect of antihistamine with or without gluten-free diet in patients with urticaria

Protocol summary

Study aim

Comparison of the therapeutic effect of antihistamine with or without gluten-free diet in patients with urticaria

Design

Clinical trial with control group, with parallel groups, blinded, randomized, phase 3 on 90 patients. The randomization function of Excel software was used for randomization.

Settings and conduct

This study is carried out after obtaining the code of ethics from Tehran Islamic Azad University of Medical Sciences in affiliated hospitals of this university. 90 samples of urticaria patients referred to the hospitals affiliated to this university who meet the study entry criteria will be selected based on random sampling. People's background information including gender, age, BMI and personal or family history of atopic diseases are collected through a pre-designed questionnaire, then patients are divided into two groups, placebo and case, according to gender, age, BMI and personal and family history of atopic diseases are divided, then the placebo group receives one vitamin B1 100mg daily and antihistamine for one month, and the case group receives gluten-free diet and antihistamine for one month and follow up the symptoms of both The group is evaluated on a weekly basis using the UAS7 form, the intensity of urticaria symptoms based on the amount of itching and the number of hives.

Participants/Inclusion and exclusion criteria

Patients referred to affiliated hospitals of Tehran Islamic Azad University of Medical Sciences Patients with urticaria The possibility of examining the patient's symptoms and the patient's cooperation

Intervention groups

Intervention group: antihistamine and gluten-free diet.
Control group: antihistamine alone.

Main outcome variables

Urticaria severity (based on urticaria activity score: UAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230709058722N1**

Registration date: **2024-02-04, 1402/11/15**

Registration timing: **prospective**

Last update: **2024-02-04, 1402/11/15**

Update count: **0**

Registration date

2024-02-04, 1402/11/15

Registrant information

Name

Farough Bazargani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 762 3971

Email address

faroughbazargani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-21, 1402/12/02

Expected recruitment end date

2024-03-21, 1403/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of antihistamine with or without gluten-free diet in patients with urticaria

Public title
The effect of gluten-free diet in the treatment of urticaria

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with urticaria
Exclusion criteria:
no possibility of examining the patient's symptoms
patient's unwillingness to cooperate in the study

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random, every urticaria patient who comes to the hospital is placed in groups through a table of random numbers that have been determined in advance. Based on that, the numbers 1, 4, 7, and... in one group and the numbers 2, 3, 5, 6, 8, and 9... in the other group will be selected as random numbers, using simple random sampling method.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Tehran
Medical Branch

Street address

Shariati St, Islamic Azad University, Tehran Medical
Branch

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2023-07-04, 1402/04/13

Ethics committee reference number

IR.IAU.TMU.REC.1402.075

Health conditions studied

1

Description of health condition studied

Chronic urticaria

ICD-10 code

L50

ICD-10 code description

Urticaria

Primary outcomes

1

Description

Urticaria severity (based on urticaria activity score: UAS)

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start

Method of measurement

UAS7: Urticaria activity can be evaluated using the UAS7 scoring system. Urticaria/pruritus scores are accumulated daily for seven days. The maximum score is 42. Score 0: no hives for 24 hours Score 0: no itching
Score 1: less than 20 hives in 24 hours Score 1: mild itching: present but not annoying or troublesome. Score 2: 20 to 50 hives during 24 hours Score 2: Moderate itching: It is troublesome but does not interfere with normal daily activities or sleep. Score 3: More than 50 hives during 24 hours Score 3: Severe itching: Severe itching, as much as which interferes with normal daily activities or sleep

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 90 samples of urticaria patients referred to the hospitals of this university who meet the inclusion criteria will be selected based on the random sampling method. The patients will be divided into two groups: placebo and case. Antihistamine for one month and following up the symptoms of both groups on a weekly basis using the UAS7 form, the intensity of urticaria symptoms is scored and evaluated based on the amount of itching and the number of hives.

Category

Treatment - Other

2

Description

Control group: A number of 90 samples of urticaria patients referred to the hospitals affiliated to this university who meet the criteria for entering the study will be selected based on the random sampling method. 100 mg daily and antihistamine for one month are investigated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhikhtegan Hospital

Full name of responsible person

Dr. Setareh Tehrani

Street address

Farhikhtegan Hospital Shahran, Tehran Tehran
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1477899679

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehrdad gholamzade

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Shariati St, Islamic Azad University, Tehran Medical
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shahabpour_golaleh@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Setareh Tehrani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Plate 9 Unit 4, Ramzan Khavarani St., Mohsen Om,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Setareh Tehrani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

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Full name of responsible person
Farough Bazargani
Position
medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Tehran
Province
Tehran
Postal code

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