

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of gluten-free diet effect on chronic urticaria

Protocol summary

Study aim

Evaluation of gluten-free diet on Chronic Urticaria in 25 patients referred to the Dermatology Clinic of Hospitals of Islamic Azad University of Medical Sciences-Tehran Unit.

Design

Non-randomized clinical trial with concurrent parallel study, controlled group trial, not-blinded and available patients.

Settings and conduct

In this Interventional study, clinical trial, which is performed as a concurrent parallel study, 50 Chronic Urticaria patients referred to dermatology clinic of Islamic Azad University of Tehran Medical Branch during the years 2016 and 2017 were selected and investigated. They were divided into two almost similar groups contains 25 patients. Gluten-free diet for one of group, and Placebo (vitamin B1 100 mg daily) was ordered for one month for another group. Both groups were followed weekly during a one month period. Then they were evaluated for response to treatment at the end of the month. In this way, the effectiveness of gluten-free diet was evaluated for their disease recovery.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- The patient's availability for follow-up for one month 2- Possibility to examine the skin with chronic urticaria 3- Chronic urticaria 4- Mild to moderate chronic urticaria 5- Age over 15 years 6- Age under 65 years No Entry- criteria: 1- Chronic physical urticaria 2- Severe chronic urticaria (frequent recurrence, generalized) 3- Chronic urticaria associated with dyspnea and/ or angioedema

Intervention groups

Intervention groups. Gluten-free diet for one of Intervention group, and Placebo (vitamin B1 100 mg daily) was ordered for one month for another group.

Main outcome variables

Clinical improvement of Chronic urticaria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180421039374N1**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **retrospective**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Shiva Bahrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3334 8269

Email address

sh.bahrami@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

2016-08-22, 1395/06/01

Actual recruitment end date

2017-09-23, 1396/07/01

Trial completion date

2017-09-23, 1396/07/01

Scientific title

Evaluation of gluten-free diet effect on chronic urticaria

Public title

Effect of gluten-free diet on chronic urticaria

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic urticaria Possibility to examine the skin with chronic urticaria Mild to moderate chronic urticaria Age over 15 years Age under 65 years The patient's availability for follow-up for one month

Exclusion criteria:

Chronic physical urticaria Severe chronic urticaria (frequent recurrence, generalized) Chronic urticaria associated with dyspnea and/ or angioedema

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Ethic committee of Islamic Azad University, Tehran
Medical Branch

Street address

Tehran Medical Branch , Islamic Azad UniversityT,
khaghani st, shariati Ave , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2016-08-16, 1395/05/26

Ethics committee reference number

IR.IAU.TMU.REC.1395.166

Health conditions studied**1****Description of health condition studied**

Chronic urticaria

ICD-10 code

L50.8

ICD-10 code description

Other urticaria

Primary outcomes**1****Description**

Clinical improvement of Chronic urticaria

Timepoint

Clinical evaluation of the severity of urticaria in the beginning of the study and 7, 14, 21 and 30 days after gluten-free diet

Method of measurement

Clinical observation of urticaria and patient inquiries

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: gluten-free diet (remove wheat, barley, cloves and food from them) for one month.

Category

Treatment - Other

2**Description**

Control group: placebo, tablet vitamin B1 ,100 mg,daily for one month

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir al-momenin hospital

Full name of responsible person

Mahmood Amerion

Street address

Amir al-momenin hospital, shirmohammadi St.,
Naziabad

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Province

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1811694784
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Email
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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Farshad Hashemian
Street address
Tehran Medical Branch , Islamic Azad UniversityT,
khaghani St., shariati Ave.
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Web page address
http://iautmu.ac.ir

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

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
Islamic Azad University
Full name of responsible person
Shiva Bahrami
Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

استادیار

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shiva Bahrami

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared with unidentifiable patients.

When the data will become available and for how long

Start the access period: 12 months after publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Analysis of data in related research

From where data/document is obtainable

Corresponding author: sh.bahrami@iautmu.ac.ir and sh.bahrami7@gmail.com

What processes are involved for a request to access data/document

Send email with attached documentation

Comments