

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of Medicinal Ma-alshaeir(herbal product based on Iranian traditional medicine) in comparison with placebo on clinical symptoms of patients with Chronic Idiopathic Urticaria: A randomized triple-blind clinical trial

Protocol summary

Study aim

Determining the effect of barley extract on clinical symptoms and quality of life in patients with Chronic Spontaneous Urticaria .

Design

Randomised, superiority, parallel group trial with triple blinded outcome assessment on 46 patients.

Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct

Patients with Chronic Idiopathic Urticaria allergy clinic of ghaem hospital are examined by immunologist and the international urticaria registry form including demographic factors, hives severity and quality of life is completed. barley extract is prescribed for 4 weeks. the specialist will review and complete the forms after 4 week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients of Chronic Idiopathic Urticaria between the ages of 18 and 60, having no history of autoimmune disease or immunodeficiency at present, willingness to participate in the study Inclusion criteria: pregnancy, previous sensitivity to medication or its components

Intervention groups

Patients use barley extract for 4 weeks. The drug is dissolved in the form of 15 cc morning and evening powder in a glass of water and is whipped. Placebo is prepared in the same shape and color and consumed by the patient for 4 weeks

Main outcome variables

clinical sign & symptom by international urticaria registry form

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210309050643N1**

Registration date: **2021-06-28, 1400/04/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-28, 1400/04/07**

Update count: **0**

Registration date

2021-06-28, 1400/04/07

Registrant information

Name

Iran saeidinejat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 8931

Email address

saeedish1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation of the effect of Medicinal Ma-alshaeir(herbal product based on Iranian traditional medicine) in comparison with placebo on clinical symptoms of patients with Chronic Idiopathic Urticaria: A randomized triple-blind clinical trial
Public title	Evaluation of the effect of Barley extract in the treatment of chronic urticaria
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Patients with chronic spontaneous urticaria, aged 18 to 60 years do not have autoimmune disease or immunodeficiency wish to participate in the study
Exclusion criteria:	pregnancy Previous hypersensitivity to the drug or any of the compounds present in the herbal medicinal product
Age	From 18 years old to 60 years old
Gender	Both
Phase	2
Groups that have been masked	• Participant • Care provider • Data analyser
Sample size	Target sample size: 46
Randomization (investigator's opinion)	Randomized
Randomization description	The randomization method in this study will be block-randomization. each block has four numbers. The sequence produced by the https://www.sealedenvelope.com/ will be provided to the researchers by the project methodologist and will be placed in sealed, opaque, and numbered envelopes. The project researcher opens one of the envelopes when each patient enters the clinic and the patient will be assigned to the group mentioned in the envelope.
Blinding (investigator's opinion)	Triple blinded
Blinding description	Placebo and druge _same packaged_ marked by specified code and consumption instruction. patient and attentive and analyzer are blind ,at the end of study outcomes decode by researcher.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Mashhad University of Medical Sciences - Biomedical Research Ethics Committee

Street address

Azadi Squair- Kalantary Street

City

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Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.099

Health conditions studied

1

Description of health condition studied

urticaria

ICD-10 code

L50

ICD-10 code description

Urticaria

Primary outcomes

1

Description

detect the effect of barley extract on clinical symptoms of CSU patients

Timepoint

At the beginning of the intervention and 4 weeks after taking the drug

Method of measurement

International Urticaria Registration Questionnaire

Secondary outcomes

1

Description

urticaria clinical symptoms score

Timepoint

At the beginning of the intervention and 4 weeks later

Method of measurement

Urticaria Activity score Questionnaire

2

Description

Quality of life of chronic urticaria patients

Timepoint

At the beginning of the intervention and 4 weeks later

Method of measurement

score of Chronic Urticaria Quality of Life questionnaire

3

Description

relapse of patients' clinical symptoms

Timepoint

At the beginning of the intervention and 4 weeks later

Method of measurement

Urticaria Control Test

Intervention groups

1

Description

Intervention group: Herbal product based on barley seeds (*Hordeum vulgare*) in a dose of 15 grams in 2 doses for 4 weeks is prescribed. The herbal product contains an aqueous extract of barley seeds which is converted into powder during the spray-drying process and presented to the patient. Patients also receive the common urticaria drug, Foxofenadine 180 mg twice daily.

Category

Treatment - Drugs

2

Description

Control group: Provide placebo powder 15 mg twice a day + Faxophenadine 180 mg twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Maryam Khoshkhui

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School of Persian and complementary medicine,
University campus, Azadi Square, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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<https://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Shahin Saeidinejat

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The data related to main outcome will be provided to the researchers upon request from corresponding author and after confirmation by him.

When the data will become available and for how long

Access starts from the time the article is published until one year later

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Access to the raw data collected in this study will be possible after obtaining permission from the lead researchers and the responsible author. Research use in the form of publishing a new article of the data in this study requires the written permission of the researchers of current study.

From where data/document is obtainable

Applicants can communicate with the person who is scientifically responsible for this research via email derakhshanar@mums.ac.ir

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

Send the request via the mentioned email and explain the reason for the request and the applicant's details and a description of possible uses Accepting or rejecting the request from the main researcher of the research by email

Comments