Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison of jujube compound herbal medicine containing jujube, coriander, fumaria, lentil and chicory with desloratadine on chronic urticaria

Protocol summary

Study aim
Comparison of the number and severity of itching, quality of life in adults with chronic urticaria before and after taking jujube and desloratadine

Design
The Phase 3 clinical trial will be conducted in a parallel, double-blind, randomized design on 60 patients. All randomization steps will be performed on the website https://ctrandomization.cancer.gov using the Clinical Trial Randomization Tool option.

Settings and conduct
This study is conducted on people with chronic urticaria in Kashan. After diagnosis and completion of the informed consent form, patients are randomly assigned to two treatment groups in a block design. Urticaria Symptoms Questionnaire (UAS) and Quality of Life (CU-Q2OL) are used at the beginning and end of the study. At the end of the study, if there is no improvement, the subjects will be placed on routine treatment. the patients, the researcher, and the statistical analyst are blinded to the treatment groups. For blinding, the drugs are in the same packaging, label, and size.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with chronic urticaria with physician approval, age 12 to 65 years; Exclusion criteria: Allergy to the drug or any of the ingredients in the herbal medicine Jujube compound, pregnancy, severe angioedema, uncontrolled cardiovascular, respiratory, hematological, renal, hepatic, immune system and connective tissue diseases.

Intervention groups
Group 1: Recipients of compound jujube syrup manufactured by Barij Essence Pharmaceutical Company containing jujube, chicory, horsetail, lentils and coriander extracts in an amount of 10 cc twice a day for one month. Group 2: Recipients of desloratadine syrup manufactured by Iran Darou Pharmaceutical Company 10 cc twice a day for one month.

Main outcome variables
Number of hives, severity of itching, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220512054829N9**
Registration date: **2026-08-04, 1405/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-04, 1405/05/13**
Update count: **0**

Registration date
2026-08-04, 1405/05/13

Registrant information

Name
Hossein Akbari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5554 0111

Email address
akbari1350_h@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-05, 1405/03/15

Expected recruitment end date
2027-01-05, 1405/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of jujube compound herbal medicine containing jujube, coriander, fumaria, lentil and chicory with desloratadine on chronic urticaria

Public title
Comparing the effects of jujube syrup with desloratadine on chronic urticaria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic urticaria with physician approval Age between 12 and 65 years
Exclusion criteria:
Allergy to desloratadine Allergy to any of the ingredients in the herbal medicine jujube compound Pregnancy Severe angioedema Having uncontrolled cardiovascular and respiratory diseases Having uncontrolled hematological diseases Having uncontrolled liver and kidney diseases Having immune system diseases Having connective tissue diseases
Age
From **12 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is performed using the permuted block randomization method, so that first all 4 blocks containing two codes A and B are prepared (6 blocks), then random blocks are selected by placement using a random number table. These blocks form a sequence of codes A and B equal to the sample size, and each code is randomly assigned to one of the groups. All randomization steps will be performed on the site https://ctrandomization.cancer.gov and using the Clinical Trial Randomization Tool option. The list of relevant codes will remain in the formulation department of Barij Essence Pharmaceutical Company until the completion of the project. This method will provide both blinding and randomization.
Blinding (investigator's opinion)
Double blinded
Blinding description
The herbal syrup under study is manufactured in the formulation department of Barij Essans Pharmaceutical Company and is identical to Desloratadine (Neotadine) syrup (manufactured by Adora Teb Iran Company) in terms of appearance, size, and color of the glass and is provided in identical packaging. Then, it is coded based on codes previously prepared using a random number table and block randomization method. And it is provided to the project implementers in a mixed form in a carton.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Faculty of Nursing & Midwifery, Health & Paramedicine, Kashan
Street address
Pezeshk Blvd, Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Approval date
2026-02-01, 1404/11/12
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1404.073

Health conditions studied

1

Description of health condition studied
Chronic urticaria
ICD-10 code
L50.9
ICD-10 code description
Urticaria, unspecified

Primary outcomes

1

Description
number of hives
Timepoint
Before starting treatment and 7 and 14 and 28 days after starting treatment
Method of measurement
Urticaria Activity Score Questionnaire (UAS)

2

Description
Itching intensity
Timepoint
Before starting treatment and 7 and 14 and 28 days after starting treatment
Method of measurement
Urticaria Activity Score Questionnaire (UAS)

3

Description
quality of life
Timepoint
Before starting treatment and 7 and 14 and 28 days after starting treatment
Method of measurement
Using the Chronic Urticaria Patients Quality of Life Questionnaire (CU-Q2OL)

Secondary outcomes

1

Description
Patient satisfaction
Timepoint
Before starting treatment and 7 and 14 and 28 days after starting treatment
Method of measurement
Urticaria Activity Score (UAS) questionnaire

Intervention groups

1

Description
Intervention group: Recipients of jujube syrup manufactured by Barij Essence Pharmaceutical Company, containing jujube, chicory, horsetail, lentils and coriander extracts, 10 cc twice a day for one month.
Category
Treatment - Drugs

2

Description
Control group: Recipients of desloratadine syrup manufactured by Iran Darou Pharmaceutical Company, 10 cc twice a day for one month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti hospital
Full name of responsible person
Marzie Heydarzadeh Arani
Street address
Pezeshk Blvd, Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 912 214 6635
Email
marz_heidar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Pezeshk Blvd, Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 913 163 1685
Fax
+98 31 5554 0029
Email
hamidi_gh@yahoo.com
Grant name
Grant code / Reference number
404159
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
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

2

Sponsor
Name of organization / entity
Barij Essence Pharmaceutical Company

Full name of responsible person
Mohammad Reza Memarzadeh
Street address
44th km of Mashhad Ardehal Road
City
Kashan
Province
Isfehan
Postal code
3795191916
Phone
+98 86 4854 0320
Fax
Email
Memarzadeh.m.r@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Barij Essence Pharmaceutical Company

Proportion provided by this source
50

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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hossein Akbari
Position
Professor of Biostatistiics
Latest degree
Ph.D.
Other areas of specialty/work
Biostatistics
Street address
Pezeshk Blvd, Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5558 9396
Email
akbari1350_h@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Marzieh Heidarzadeh Arani
Position
Professor of Pediatric Allergy and Immunology
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric asthma and allergies
Street address
Pezeshk Blvd, Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5558 9396
Email
marz_heidar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hossein Akbari
Position
Professor of Biostatistics
Latest degree
Ph.D.
Other areas of specialty/work
Biostatistics
Street address
Pezeshk Blvd, Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5558 9396
Email
akbari1350_h@yahoo.com

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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available