Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the Efficacy of Plantago major Aqueous Extract with Cetirizine in Treatment of Acute Urticaria: a Double-blind, Randomized Controlled Trial

Protocol summary

Summary

In this prospective process, patients with acute urticaria who were referred to Razi, Loghman, and Shohadaye Tajrish hospitals in 1392 are studied. Inclusion criteria are age between 10 and 70 years old, negative history of autoimmune or immunodeficiency diseases, negative history of any specific drugs and willingness to participate in the study. Also, patients who received antihistaminic drugs or combination of corticosteroids a month before the trial, pregnant women, and patients with previous allergy to antihistamines or any ingredients in the herbal medicinal products will be excluded from the study. All patients will be informed about the project process and benefits and side effects of the drugs and the informed consent in order to participate in the project will be obtained.Then, patients will be divided into 2 groups, randomly. In the first group, plantago major aqueous extract in form of syrup will be administered twice a day and in the second group cetirizine syrup will be administered in the same way (Cetirizine is recommended as the first line of the second-generation antihistamine drugs in the treatment protocol of urticaria). A check list will be provided for each patient to document every urticaria lesions which have been experienced during the day. Patients will be examined on days 3 and 15 in person and on days 6 and 9 via phone call. In each check up, the scratching , resistance to therapy, and side effects will be examined. At the end of the treatment, patient's satisfaction will be questioned. The collected data will be analyzed by SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082914519N1**

Registration date: **2014-04-25, 1393/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-25, 1393/02/05

Registrant information

Name

Mohammad Ali Yazdian

Name of organization / entity

Ancient Medicine Faculty of Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2228 2526

Email address

yazdian980@gmail.com

Recruitment status

Recruitment complete

Funding source

personal funding

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Efficacy of Plantago major Aqueous

Extract with Cetirizine in Treatment of Acute Urticaria: a Double-blind, Randomized Controlled Trial

Public title
Comparison the Effects of Plantago major Aqueous Extract with Cetirizine in Treatment of Acute Urticaria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 10 to 70 years old patients; no history of autoimmune or immunodeficiency disease; negative drug history; willingness to participate in the study
Exclusion criteria: received antihistaminic drugs, or combination of corticosteroids a month before the trial; pregnancy; previous allergy to Antihistamines or any of the ingredients in the herbal medicinal products; unwillingness to participate in the study
Age
From **10 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Both patients and the researchers (who will examine the outcomes of the study) will be blind to the drugs used in the trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Building no.2, Shahid Beheshti University of Medical Sciences, Parvane St, Yaman St, Shahid Chamran Boulevard
City
Tehran
Postal code
Approval date
2013-12-29, 1392/10/08
Ethics committee reference number
144

Health conditions studied

1

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

Primary outcomes

1

Description
amount of itching, drug resistance, and side effects
Timepoint
days 3 and 15
Method of measurement
visiting a dermatologist at the clinic

2

Description
number of urticarial lesions
Timepoint
every day
Method of measurement
Asking the patient

3

Description
amount of itching, drug resistance, and side effects
Timepoint
days 9 and 6
Method of measurement
Asking the patient

4

Description
satisfaction of treatment
Timepoint
At the end of the follow ups
Method of measurement
Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description

The control group was treated with cetirizine syrup (Citirizine Tolid Daro Tehran Company), 5cc per day for 15 days.

Category

Treatment - Drugs

2

Description

the first group received 10% Plantago major aqueous extract, 5cc per day for 15 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi, Tajrish and Loghman Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ancient Medicine Faculty,Vice chancellor for research, Shahid Beheshti University of Medical Science

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Parvane St, Yaman St, Shahid Chamran Boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ancient Medicine Faculty,Vice chancellor for research, Shahid Beheshti University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ancient Medicine Faculty, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Yazdian

Position

PhD Student

Other areas of specialty/work

Street address

Apartment no.8, Shams Avenue, Vali Asr St

City

Tehran

Postal code

Phone

+98 21 8877 3525

Fax

Email

yazdian980@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ancient Medicine faculty of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahmoud Khodadoost

Position

professor of the faculty

Other areas of specialty/work

Street address

Ancient Medicine faculty of Shahid Beheshti University of Medical Sciences, Shams Avenue, Tavanir, Vali Asr St

City

Tehran

Postal code

Phone

+98 21 8877 3525

Fax

Email

mkhodadoost@lmo.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Ali Yazdian

Position

PhD Student

Other areas of specialty/work

Street address

Apartment no.8, Shams Avenue, Vali Asr St

City

Tehran
Postal code
Phone
00
Fax
Email
yazdian980@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty