Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of probiotic and antihistamine therapy with antihistamine therapy alone in reducing the number of urticaria and pruritus in chronic urticaria patients

Protocol summary

Study aim

Comparison of the effectiveness, complications, tolerance and satisfaction of probiotic and antihistamine therapy with antihistamine therapy alone in reducing the number of urticaria and pruritus in chronic urticaria patients

Design

A randomized controlled clinical trial with parallel groups

Settings and conduct

Being carried out at the dermatology department of Rasool-E-Akram Hospital. At first they complete questionnaire 1. It includes demographic information including age, sex, occupation, weight, marital status, contact number and address, duration of hives, number of days per week, as well as previous antihistamine use history and type. Completion of Questionnaire 2 which is the Number and Severity of Hives and Questionnaire 3 related to quality of life Targeted trials Grouping patients into two groups randomly Patients should be treated for 8 weeks. First of all at the first visit then eighth week questionnaires number 2 and 3 will be completed by physicians. Without any blinding

Participants/Inclusion and exclusion criteria

Inclusion criteria: urticaria in at least two days a week for at least 6 weeks; Age between 18 and 45 years. Non-Inclusion criteria: Serious comorbidities; Taking any drug other than antihistamines; Having vasculitis.

Intervention groups

Intervention group: For this group of patients, treatment includes only antihistamines.Two antihistamines is given twice daily and the type of them is prescribed based on the patient's condition and tolerance.These antihistamines are selected from cetirizine, desloratadine (neotadine) and fexofenadine. In addition, two lactocare capsules are prescribed too which are containing two probiotics. Control group: Second group will be treated only with the antihistamines listed above.

Main outcome variables

Pruritus severity; urticaria activity score over 7 days (UAS7); Number of hives; Complications; tolerance of treatment; satisfaction; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190825044613N1**
Registration date: **2019-12-15, 1398/09/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-15, 1398/09/24**
Update count: **0**

Registration date

2019-12-15, 1398/09/24

Registrant information

Name

Shokoufeh Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6650 6773

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of probiotic and antihistamine therapy with antihistamine therapy alone in reducing the number of urticaria and pruritus in chronic urticaria patients

Public title

Effect of Probiotic in reducing urticaria and pruritus in people with chronic urticaria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

For at least two days of week patients must have urticaria lesions and these lesions must remain for at least 6 weeks. Age between 18 to 45 years old

Exclusion criteria:

Serious comorbidities (such as malignancies, mental illness, hepatitis, endocrine or other acute and chronic systemic diseases) Taking any drug other than antihistamines Patients with vasculitis Patients with urticaria due to autoimmune diseases A history of severe gastrointestinal diseases such as indigestion and malabsorption Patients taking corticosterone for any reason A history of asthma and allergies in the patients and their first degree relatives Patients with severe mental problems

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two main groups after first visit. Patients with odd number in the list are included in to group 1 and patients with even number are included in group 2.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-02-26, 1397/12/07

Ethics committee reference number

IR.IUMS.FMD.REC.1398.129

Health conditions studied

1

Description of health condition studied

Hives

ICD-10 code

L50.9

ICD-10 code description

Urticaria, unspecified

Primary outcomes

1

Description

Itching severity

Timepoint

first visit - 8 Week after treatment

Method of measurement

Questionnaire and visit

2

Description

urticaria activity score over 7 days (UAS7)

Timepoint

first visit -- 8 Week after treatment

Method of measurement

Questionnaire and visit

3

Description

Number of hives

Timepoint

first visit - 8 Week after treatment

Method of measurement

Questionnaire and visit

Secondary outcomes

1

Description
Quality of Life
Timepoint
first visit snd 8 Week after treatment
Method of measurement
dermatology Quality Life Index

2

Description
Complications
Timepoint
8 Week after treatment
Method of measurement
interview

3

Description
tolerance of treatment and satisfaction
Timepoint
8 Week after treatment
Method of measurement
interview

Intervention groups

1

Description
Intervention group: For the first group of patients, treatment includes only antihistamines.Two antihistamines is given twice daily and the type of them is prescribed based on the patient's condition and tolerance.These antihistamines are selected from cetirizine, desloratadine (neotadine) and fexofenadine. In addition, two lactocare capsules are prescribed too which are containing two probiotics.
Category
Treatment - Drugs

2

Description
Control group: The second group of patients only received antihistamines. Two antihistamines is given twice daily and the type of them is prescribed based on the patient's condition and tolerance.These antihistamines are selected from cetirizine, desloratadine (neotadine) and fexofenadine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool-E-Akram hospital
Full name of responsible person
Shokoufe Sharifi
Street address
Rasoul-E-Akram Hospital, Maziar Mansouri street, Sattarkhan street, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Shokoufeh Sharifi
Position
Dermatology Resident
Latest degree
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Other areas of specialty/work
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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
All potential data can be shared after publication of result
When the data will become available and for how long
At the end of data collection period until the publication of results
To whom data/document is available
Only doctors and medical students
Under which criteria data/document could be used
Only when people intend to research about this topic
From where data/document is obtainable
To the scientific and executive members of the project
What processes are involved for a request to access data/document
Communicate with the scientific and executive authorities of the project - Submiting their official letter from research centers -using the patient's information only at designated center - Submiting their final report obtained by information.
Comments