Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of intranasal corticosteroids in adults with chronic idiopathic urticaria with a positive prick test with airborne allergens.

Protocol summary

Study aim
Determining the effectiveness of intranasal corticosteroids in adults with idiopathic urticaria and positive prick test with airborne allergens

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 69 patients. The rand function of Excel software is used for randomization.

Settings and conduct
Patients are selected from the Asthma and Allergy Clinic of Dr. Ismailzadeh. Concealment will be done using sealed envelopes.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients must be older than eighteen years. Patients must have a diagnosis of idiopathic urticaria and positive prick test results for airborne antigens. Exclusion Criteria: Patients who are under treatment other than antihistamines by a doctor specializing in asthma and allergies. Patients who had serious side effects due to corticosteroids before the start of the study. Patients who have serious side effects caused by the use of corticosteroids during the study period.

Intervention groups
The intervention group will be treated with Nasal Budesonide (with a dose of 32 micrograms per spray) twice a day. The specific corticosteroid and dose will be determined based on previous studies and standard clinical practice. Participants in this group will be instructed on the correct method of administration and compliance will be monitored throughout the study period.

Main outcome variables
Primary outcome measures include the frequency and severity of urticaria symptoms, which are evaluated using valid scoring systems such as the Urticaria Activity Score and the Urticaria Severity Score. Secondary outcome measures will include the impact of urticaria on quality of life and daily activities, which will be evaluated using age-appropriate validation questionnaires.The quality of life is measured and announced at baseline and six months after taking the drug/placebo

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231126060193N1**
Registration date: **2024-01-12, 1402/10/22**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-12, 1402/10/22**
Update count: **0**

Registration date
2024-01-12, 1402/10/22

Registrant information
Name
Hassan Mohtadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-08, 1402/08/17
Expected recruitment end date
2024-06-08, 1403/03/19
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of intranasal corticosteroids in adults with chronic idiopathic urticaria with a positive prick test with airborne allergens.

Public title
The Role of Intranasal Corticosteroids in the Management of Chronic Idiopathic Urticaria with Positive Skin Prick Test to Airborne Allergens
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion Criteria:Patients must be older than eighteen years.Patients must have a diagnosis of idiopathic urticaria and positive prick test results for airborne antigens.Patients should be selected from adult allergy clinics.Patients must give their informed consent to participate in the study.
Exclusion criteria:
Exclusion criteria:Patients who are under treatment other than antihistamines by a doctor specializing in asthma and allergies.Patients who cannot participate during six months.Patients who had serious side effects due to corticosteroids before the start of the study.Patients who have serious side effects caused by the use of corticosteroids during the study period.Patients who experience serious side effects from corticosteroids during the study period.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **69**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants in this study will include adult patients aged 18 years and older who have been diagnosed with idiopathic urticaria based on clinical criteria and have tested positive for air allergens in the prick test. Participants will be randomly selected from adult allergy clinics using simple random sampling) . Patients are divided into two intervention and placebo groups by researchers using sealed envelopes that cannot be seen in light. . Informed consent will be obtained from the participants.
Blinding (investigator's opinion)
Double blinded
Blinding description
Using computer randomization codes, participants will be randomly assigned to two intervention groups or control groups. Allocation is concealed from researchers, participants, and their families to ensure blinding. A placebo intranasal spray will be provided to the control group to maintain blinding for the duration of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Zand st
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2023-11-07, 1402/08/16
Ethics committee reference number
IR.SUMS.MED.REC.1402.367

Health conditions studied

1

Description of health condition studied
Chronic Idiopathic Urticaria
ICD-10 code
L50.1
ICD-10 code description
Idiopathic urticaria

Primary outcomes

1

Description
Primary outcome measures include the frequency and severity of urticaria symptoms, which are evaluated using valid scoring systems such as the Urticaria Activity Score and the Urticaria Severity Score.
Timepoint
At the beginning of the study (before the start of the intervention) and six months after the start of the study
Method of measurement
Quality of life questionnaire related to chronic urticaria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will be treated with Nasal Budesonide (with a dose of 32 micrograms per spray) twice a day. The specific corticosteroid and dose will be determined based on previous studies and standard clinical practice. Participants in this group will be instructed on the correct method of administration and compliance will be monitored throughout the study period.
Category
Treatment - Drugs

2

Description
Control group: The control group receives a 0.9% sodium chloride intranasal spray, which is very similar to the active treatment but does not contain any active corticosteroids. Placebo spray is administered according to the same schedule and instructions as the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Esmailzadeh Asthma and Allergy Clinic
Full name of responsible person
Hossein Esmaeelizade
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadhashem Hashempour
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Email
Hashempor@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Hossein Esmaeilzadeh
Position
Associate professor
Latest degree
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Person responsible for updating data

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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 data can be shared after de-identifying individuals.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Only researchers working in academic and scientific institutions
Under which criteria data/document could be used
There is no special condition, with the permission of the corresponding author, people can use the data in any way they need.
From where data/document is obtainable
To the corresponding author Dr. Hossein Esmailzadeh at the email address: esmailzadeh_ho@yahoo.com
What processes are involved for a request to access data/document
After checking the identification documents and how to use them according to the applicant proposal . The corresponding author will send the data to the individual (about three months).
Comments