

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 71 3636 2525

Email address

mohtadi.hasan64@yahoo.com

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 Esmaeilzade

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Ordibehesht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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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Other areas of specialty/work

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Person responsible for updating data

Contact

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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