

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparative survey of the effectiveness of topical injection of Triamcinolone and Jelfum with Triamcinolone on reducing the symptoms of patients with allergic rhinitis

#### Protocol summary

##### Study aim

Determining the effectiveness of triamcinolone and the combination of jelfum with triamcinolone on reducing the symptoms of patients with allergic rhinitis

##### Design

This study is a randomized controlled clinical trial of the parallel type of phase 1. which the allocation of individuals in the group is equal and random, in other words, the allocation ratio in this study is equal to one. For random allocation of patients in each group, the block randomization method with unequal blocks (for example, 2, 4, 6, etc.) will be used and in each block, an equal number of each group will be placed.

##### Settings and conduct

Patients with allergic rhinitis referred to the clinic of Imam Khomeini Hospital in Kermanshah city, are divided into 3 groups and the first group is given triamcinolone by injection in the septum, In the second group, Jelfum impregnated with triamcinolone is placed intranasally in the middle meatus of the nose, and the third group is routinely treated. And after some time by the project assistant, the patient's symptoms are recorded and compared in all 3 groups. The study is a parallel randomized controlled clinical trial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: ARIA criteria for the diagnosis of allergic rhinitis Exclusion criteria: history of rhinoplasty, anatomical disorders of the nose, persistent asthma, Prolonged use of corticosteroids, tuberculosis, diabetes, other chronic systemic diseases and pregnancy

##### Intervention groups

In the first group is given Triamcinolone by injection into the septum, the second group, Jelfum impregnated with triamcinolone is placed intranasally in the middle meatus of the nose, and the third group is routinely treated.

##### Main outcome variables

Sneezing; runny nose; Nasal congestion; Itchy nose

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210915052490N1**

Registration date: **2021-10-10, 1400/07/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-10, 1400/07/18**

Update count: **0**

##### Registration date

2021-10-10, 1400/07/18

##### Registrant information

##### Name

Amrollah Dehghanifrouzabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3823 4604

##### Email address

amrollah.dehghani@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-04, 1400/06/13

##### Expected recruitment end date

2021-11-11, 1400/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparative survey of the effectiveness of topical injection of Triamcinolone and Jelfum with Triamcinolone on reducing the symptoms of patients with allergic rhinitis

## Public title

Effect of Triamcinolone and Jelfum in reducing the symptoms of allergic rhinitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

ARIA Criteria Diagnosis of allergic rhinitis

### Exclusion criteria:

History of rhinoplasty Anatomical disorders of the nose  
Persistent asthma Prolonged use of corticosteroids  
Tuberculosis Diabetes Chronic systemic diseases  
Pregnancy

## Age

No age limit

## Gender

Both

## Phase

1

## Groups that have been masked

*No information*

## Sample size

Target sample size: **45**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization method: Block randomization method with unequal blocks (for example 2, 4, 6, etc.) will be used - Randomization unit: individual - How to build a random sequence: An equal number of each group will be placed in each block. In this way, first the list of all permutations related to the size of the desired block is determined and then will be randomly selected as many as the number of sample from permutation - Randomization tool: Random generation and selection of permutations done using reputable sites generate a block randomization list. Such as <https://www.sealedenvelope.com> - Hide method: use the envelope in the package

## 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

Research Ethics Committee of Kermanshah University of Medical Sciences

#### Street address

Deputy of Research and Technology- Building No. 2 - Shahid Beheshti Boulevard - Kermanshah

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6715847141

#### Approval date

2021-08-31, 1400/06/09

#### Ethics committee reference number

IR.KUMS.REC.1400.464

## Health conditions studied

## 1

### Description of health condition studied

Allergic Rhinitis

### ICD-10 code

J30.8

### ICD-10 code description

Other allergic rhinitis

## Primary outcomes

## 1

### Description

Sneezing

### Timepoint

At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the intervention.

### Method of measurement

Based on question from the person (The rate of patient sneezing based on the number of episodes of the patient's daily sneezing)

## 2

### Description

runny nose

### Timepoint

At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the intervention.

### Method of measurement

Based on a question from the person (number of sheets of tissue paper consumed by the patient per day)

## 3

### Description

Nasal congestion

### Timepoint

At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the intervention.

**Method of measurement**

Based on the scores that patient gives to these symptoms from zero to three

**4****Description**

Itchy nose

**Timepoint**

At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the intervention.

**Method of measurement**

Based on the scores that patient gives to these symptoms from zero to three

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Half a cc of Triamcinolone 40 ml Per mg is injected into the septum.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Jelfum impregnated with triamcinolone is placed Intranasally in the Middle meatus of the nose Both nostril nasal By Zero degree endoscope

**Category**

Treatment - Drugs

**3****Description**

Control group: This group is treated routinely. Routine treatment will be washing serum and then nasal fluticasone spray, 2 puffs per nostril, every 6 hours (200 mg per day).

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital in Kermanshah

**Full name of responsible person**

Amrollah Deghani

**Street address**

Imam Khomeini Hospital - Transportation Street - Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6718743161

**Phone**

+98 83 3728 5054

**Email**

ihosp@kums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Reza Khodarahmi

**Street address**

Deputy of Research and Technology- Building No. 2 - Shahid Beheshti Boulevard - Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6719995364

**Phone**

+98 83 3838 4185

**Email**

rkhodarahmi@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Amrollah Deghani

**Position**

Assistant Professor of Otorhinolaryngology

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

School of Medicine - University Street - Shahid  
Shiroodi Boulevard - Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714869914

**Phone**

+98 83 3427 4618

**Email**

amrollah.dehghani@kums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Amrollah Dehghani

**Position**

Assistant Professor of Otorhinolaryngology

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Postal code**

6714869914

**Phone**

+98 83 3427 4618

**Email**

amrollah.dehghani@kums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Sharmin Rahmani

**Position**

Researcher of Imam Khomeini Hospital Research Unit,

Kermanshah

**Latest degree**

Master

**Other areas of specialty/work**

Biostatistics

**Street address**

Imam Khomeini Hospital - Transportation Street -  
Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6718743161

**Phone**

+98 83 3727 2049

**Email**

sh.rahmani90@yahoo.com

**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 is shared

**When the data will become available and for how long**

The access period starts one year after the results are published

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Use for future research

**From where data/document is obtainable**

Kermanshah University of Medical Sciences

**What processes are involved for a request to access data/document**

By Email

**Comments**