

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Comparison of Efficacy of Ozone Therapy with Routine Medical Treatment On The Severity Of Allergic Rhinitis.

Protocol summary

Study aim

The Purpose of this Study is to compare the Effectiveness of Ozone Therapy with Routine Medical Treatment in Patients with Allergic Rhinitis

Design

Parallel, single-blind, randomized clinical trial

Settings and conduct

40 Patients with Allergic Rhinitis that were referred to the manager's clinic of Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Patients will be divided into two groups. Patients of the control group will receive antihistamine. Patients of the treatment group will receive antihistamine and undergo ozone therapy. . The changes of disease severity will determine and compare in patients at the beginning and at the end of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteriaes: Having Allergic Rhinitis and age over 12 years. Exclusion criteriaes: Any Respiratory and non-respiratory inflammation such as infection, Recent massive surgery, severe pulmonary or renal disease, alcohol abuse, sever addiction, uncontrolled diabetes, cancer, autoimmune diseases

Intervention groups

Patients will be divided into two groups. So patients in the treatment group will undergo ozone therapy and classical allergy treatment (oral Cetirizine10 mg daily plus nasal Mometasone spray every 12 hours in every nasal cavity), and patients in the control group will receive only Antihistamines (classical treatment). The physician will examine the patients and based on the clinical and paraclinical findings will fill the questionnaire for any of them. Patients will undergo any treatment for 3 months. Paraclinical diagnosis is performed by doing a specific IgE measurement for types of inhaler allergens by ELISA. For each patient, at least 15 allergens will check. Ozone therapy is performed in the form of minor autohemotherapy, in which about 20 doses of 10-20 micrograms of ozone with 10 ml of peripheral whole

blood of the patient are mixed and injected intramuscularly in daily intervals. The effect of treatment in both groups will be evaluated by comparing the severity of the disease initially, and after 3 months at the end of the treatment.

Main outcome variables

The severity of the disease in both groups will be determined and compared at the beginning and at the end of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171105037262N2**

Registration date: **2017-12-01, 1396/09/10**

Registration timing: **prospective**

Last update: **2017-12-01, 1396/09/10**

Update count: **0**

Registration date

2017-12-01, 1396/09/10

Registrant information

Name

mohammadhossein pourhanifeh

Name of organization / entity

kashan university of medical science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

research assistance of kashan university of medical science

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Efficacy of Ozone Therapy with Routine Medical Treatment On The Severity Of Allergic Rhinitis.

Public title

Efficacy of Ozone Therapy on Allergic Rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Allergic Rhinitis Age over 12 years

Exclusion criteria:

Any Respiratory and non-respiratory inflammation such as infection Recent Massive Surgery Severe Pulmonary or Renal Disease Alcohol Abuse Sever Addiction Uncontrolled Diabetes Cancer Autoimmune diseases

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After specifying the sample size, the first four blocks of A and B letters are formed (6 blocks). Then, each of the blocks is numbered 1 to 6 and based on the selected numbers from random numbers table, we form a sequence of blocks, in which the letters A and B are located, and then randomly one of the letters are considered as the drug group and the other letter as the control group. This method is referred to as "Termuted Blocked Randomization".

Blinding (investigator's opinion)

Single blinded

Blinding description

Since this is a single-blind study, our blindness would be single-blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Science

Street address

Ghotb-e-Ravandi Blvd, Kashan

City

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Isfahan

Postal code

8715988141

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.46

Health conditions studied**1****Description of health condition studied**

Allergic rhinitis

ICD-10 code

J30.1

ICD-10 code description

Allergic rhinitis due to pollen

Primary outcomes**1****Description**

Disease severity

Timepoint

At the beginning of the intervention

Method of measurement

Questionnaire

2**Description**

IgE

Timepoint

At the beginning of the intervention

Method of measurement

ELISA

Secondary outcomes**1****Description**

Disease severity

Timepoint

12weeks after intervention

Method of measurement

Questionnaire

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

Intervention group: Patients in this group, in addition to the medical treatment, will benefit from minor autohemotherapy with appropriate dosage and injection intervals and standard protocol.

Category

Treatment - Drugs

2**Description**

Control group: oral Cetirizine 10 mg daily plus nasal spray mometasone every 12 hours a puff in each nasal cavity

Category

Treatment - Drugs

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

Shahid Beheshti hospital

Full name of responsible person

Hassan Nikoueinejad

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

Kashan University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Kashan 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hassan Nikoueinejad

Position

Associate professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available