Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 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 recieve antihistamine. Patients of the treatment group will recieve 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
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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
Kashan
Province
Isfehan
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
Street address
Ghotb-e-Ravandi Blvd, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotb-e-Ravandi Blvd, Kashan
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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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Other areas of specialty/work
Immunology
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Person responsible for updating data

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Other areas of specialty/work
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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