

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluating the effects of standardized hydroalcoholic extract of oat seed (*Avena sativa* L.) capsule as adjunctive treatment in allergic rhinitis

Protocol summary

Study aim

Evaluating the effects of standardized hydroalcoholic extract of oat seed (*Avena sativa* L.) capsule as adjunctive treatment in allergic rhinitis.

Design

This study is a randomized, double-blind clinical trial with a parallel group design of 38 patients

Settings and conduct

The eligible patients are selected from Afzalipour Hospital of Kerman. Randomization is by block randomization with a block size of four. Participants and physicians are blinded to intervention assignment. For blinding, *Avena sativa* L. capsule and placebo have the same shape, color and outer packaging.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People in the 18-65 age range with allergic rhinitis, Exclusion criteria: Pregnancy, nasal polyps, corticosteroid use in the past 4 weeks, antihistamine use in the past one week, having underlying medical conditions especially autoimmune and celiac diseases and allergy to 2nd generation antihistamines and oats.

Intervention groups

The treatment group received a 300 mg capsule containing *Avena sativa* extract twice daily and the control group received the same placebo in terms of shape, color, and packaging with the same dose of the treatment group.

Main outcome variables

The number of eosinophils in nasal smears are counted before beginning the treatment and at the end of the second week of treatment. Symptoms of allergic rhinitis are recorded by asking the patients before beginning the treatment and at the end of the second week of treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110310006026N12**
Registration date: **2019-11-30, 1398/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-30, 1398/09/09**

Update count: **0**

Registration date

2019-11-30, 1398/09/09

Registrant information

Name

Fatemeh Dabaghzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of standardized hydroalcoholic extract of oat seed (*Avena sativa* L.) capsule as adjunctive treatment in allergic rhinitis

Public title
Effect of Avena sativa L. in treatment of allergic rhinitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People aged 18 to 65 years With a diagnosis of allergic rhinitis

Exclusion criteria:
Pregnancy Nasal polyps Corticosteroid use in the past 4 weeks Antihistamine use in the past one week Having underlying medical conditions especially autoimmune and celiac diseases Allergy to 2nd generation antihistamines and oats

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
The eligible participants are allocated to one of the two study groups (intervention or placebo) in a 1:1 ratio. Randomization is by block randomization with a block size of four. Randomization is performed at individual level. For allocation concealment, a person (not involved in the trial) generates allocation sequence

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and physician are blinded to intervention assignment. For blinding, Avena sativa L. capsule and placebo have the same shape, color and outer packaging.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address

Beginning of Jahad Blvd., Tahmasebad Fourways

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2019-10-23, 1398/08/01

Ethics committee reference number
IR.KMU.REC.1398.354

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
The number of eosinophils in nasal smears

Timepoint
Before beginning the treatment and at the end of the second week of treatment

Method of measurement
Counting the number of eosinophils in nasal smears

2

Description
Symptoms of allergic rhinitis

Timepoint
Before beginning the treatment and at the end of the second week of treatment

Method of measurement
Recording symptoms of allergic rhinitis by asking the patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The treatment group received a 300 mg capsule containing Avena sativa extract twice daily for 14 days.

Category
Treatment - Drugs

2

Description

Control group: The control group received 300 mg of placebo twice daily for 14 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzali Pour hospital of Kerman

Full name of responsible person

Fatemeh Dabaghzadeh

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Haft bagh high way

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhtyi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Dabaghzadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available