Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
+98 34 3132 5034

Email address
dabaghzadeh@razi.tums.ac.ir

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
Street address
Haft bagh high way
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5212
Email
fatemeh.dabaghzadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhtyi
Street address
Beginning of Jahad Blvd., Tahmasebad Fourways
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3815
Email
abpardakhty@kmu.ac.ir
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
Street address
Faculty of Pharmacy, Kerman University of Medical Sciences , Haft Bagh ave, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5034
Fax
+98 34 3132 5003
Email
fatemeh.dabaghzadeh@gmail.com

Person responsible for scientific 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
Street address
Faculty of Pharmacy, Kerman University of Medical Sciences , Haft Bagh ave, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5034

Fax
+98 34 3132 5003
Email
fatemeh.dabaghzadeh@gmail.com

Person responsible for updating data

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
Street address
Faculty of Pharmacy, Kerman University of Medical Sciences , Haft Bagh ave, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5034
Fax
+98 34 3132 5003
Email
fatemeh.dabaghzadeh@gmail.com

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