

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of sesame oral immunotherapy effect for desensitization in patients with sesame anaphylaxis

Protocol summary

Study aim

determine the effect of desensitization in patients with sesame anaphylaxis

Design

According to the notification to allergist specialists, patients referred to our clinic & samples are selected sequentially among them. the sample size is estimated 10

Settings and conduct

oral immunotherapy in two phases: induction phase (with injection of two doses of omalizumab) in 4 weeks with weekly incremental increase of sesame according to protocol until reaching to target dose of 5 gram of sesame protein in Rasool hospital allergy clinic & continued target dose at home for 4 months in maintenance phase

Participants/Inclusion and exclusion criteria

Inclusion criteria: positive oral food challenge with sesame tahini in patients with sesame anaphylaxis history with or without positive skin prick, skin prick to prick or specific IgE sesame tests. Exclusion criteria: 1. age less than 4 years 2. history of cardiovascular disease 3. beta blocker or ACEI drug usage 4. severe or uncontrolled asthma 5. infectious or immune deficiency disease 6. unwillingness of patient

Intervention groups

Initially, OFC will be done to confirmation of diagnosis in all patients. the patients with positive OFC are selected for treatment. Immunotherapy has two phases. induction phase in 4 weeks with weekly incremental increase of sesame. in second phase (maintenance) patients continue to consume target dose at home for 4 months. At the end of the fourth month to determine of success of desensitization, OFC will be done again.

Main outcome variables

desensitization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181002041210N1**

Registration date: **2018-10-18, 1397/07/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-18, 1397/07/26**

Update count: **0**

Registration date

2018-10-18, 1397/07/26

Registrant information

Name

Fereshteh Salari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2383

Email address

drfereshtehsalari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sesame oral immunotherapy effect for desensitization in patients with sesame anaphylaxis

Public title

Evaluation of desensitization in patients with sesame anaphylaxis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

positive oral food challenge with consumption of sesame tahini(OGHAB HALVA company) in patient with sesame anaphylaxis history with or without positive skin prick,skin prick to prick or specific IgE sesame tests

Exclusion criteria:

age less than 4 years history of cardiovascular disease beta blocker or ACEI drug usage severe or uncontrolled asthma infectious or immune deficiency disease unwillingness of patient

Age

From **4 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences,Near the Milad Tower,Hemmat Highway,Tehran,Iran

City

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Province

Tehran

Postal code

1449614535

Approval date

2018-03-07, 1396/12/16

Ethics committee reference number

IR.IUMS.FMD.REC1396.9511568001

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

sesame anaphylaxis

ICD-10 code

T78

ICD-10 code description

Anaphylactic shock due to adverse food reaction

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

sesame anaphylaxis in oral food challenge

Timepoint

Evaluation of sesame anaphylaxis in the beginning of the study(before intervention) and 4 months after the end of immunotherapy

Method of measurement

oral food challenge test

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

serum specific sesame immunoglobulin E level

Timepoint

in the beginning of the study(before intervention) and 4 months after the end of immunotherapy

Method of measurement

ImmunoCAP specific IgE test

2**Description**

size of wheal in skin prick test

Timepoint

in the beginning of the study(before intervention) and 4 months after the end of immunotherapy

Method of measurement

ruler

3**Description**

size of wheal in skin prick to prick test

Timepoint

in the beginning of the study(before intervention) and 4 months after the end of immunotherapy

Method of measurement

ruler

Intervention groups

1

Description

Intervention group: at first all patients receive two doses of omalizumab (anti IgE antibody) 150 mg by subcutaneous injection 4 weeks before starting treatment and second dose at the beginning of the immunotherapy. Immunotherapy in two phases: induction phase in 4 weeks with weekly incremental increase of sesame tahini (OGHAB HALVA company) according to protocol until reaching to target dose of 5 gram of sesame protein in Rasool hospital allergy clinic & continued daily consumption of target dose at home for 4 months in maintenance phase. During the study daily telephone follow-up calls for patients will be done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Fereshteh Salari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Iran University of Medical Sciences

Full name of responsible person

Fereshteh Salari

Position

Fellowship of allergy & clinical immunology

Latest degree

Specialist

Other areas of specialty/work

allergy & clinical immunology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Fereshteh Salari

Position

MD, pediatrician, Allergy & clinical immunology Fellow

Latest degree

Specialist

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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

Yes - There is 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

Not applicable

Data Dictionary

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

Title and more details about the data/document

After finishing study and publication of paper about publication of data will be decided

When the data will become available and for how long

After finishing study and publication of paper

To whom data/document is available

Academic researcher

Under which criteria data/document could be used

After finishing study and publication of paper will be decided how to publish data

From where data/document is obtainable

After finishing study and publication of paper will be decided how to publish data

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

After finishing study and publication of paper will be decided how to publish data

Comments

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fereshteh Salari

Position

Fellowship of allergy & clinical immunology

Latest degree

Specialist

Other areas of specialty/work

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