

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effectiveness of oral immunotherapy with egg white for desensitizing the patients with IgE mediated sensitization to egg white and comparison with the control group

Protocol summary

Study aim

Determining the Effect of Oral Immunotherapy for Desensitizing Patients with IgE-mediated sensitization to Egg white regarding passing the oral food challenge with egg white
Determining the Effect of Oral Immunotherapy for Desensitizing Patients with IgE-mediated sensitization to Egg white regarding Specific IgE concentration to Egg white and Ovomucoid
Determining the Effect of Oral Immunotherapy for Desensitizing Patients with IgE-mediated sensitization to Egg white regarding Specific IgG4 concentration to Egg white and Ovomucoid
Determining the Effect of Oral Immunotherapy for Desensitizing Patients with IgE-mediated sensitization to Egg white regarding change in Skin Prick Test (SPT)

Design

Randomized clinical trial with random number table with control group and single blind

Settings and conduct

The patients referring to Department of Asthma and Allergy, Rasool Akram Hospital, and Jahad Clinic with an allergy to egg white up to 2 hours after ingestion and positive Skin Prick test to Egg white enter the study. All patients aged 4 years and older who have a history of IgE-mediated hypersensitivity to egg white enter in the study. At the first step, oral food challenge will be done for the subjects without a clear IgE mediated reaction to egg white in the last 6 months. The subjects with a positive reaction to OFC will be included in the study. At the beginning of the study, the skin prick test (SPT) will be performed for egg white, egg yolk, and five major food allergens including wheat, soy, milk, peanut, fish, and sesame. The baseline concentration of specific IgE and IgG4 to egg white and ovomucoid will be measured. These tests will be repeated at the end of the maintenance phase (after 6 months). The patients were randomly divided into two groups: egg white and the placebo group. Three phase including an initial dose

escalation during 5 days of hospitalization, to continue the use of received dose at home, to increase the dose up to achieve maintenance dose and maintain dose after 6 months according to the protocol of use of pasteurized raw egg white(produced by Telavang Co.). To escalate the dose in build-up phase, the patients will be hospitalized for 5 days in Rasool Akram Hospital. Obviously, during the hospitalization and the build-up phase, all treatment will be available to manage the possible attack of an anaphylactic reaction. For the safety of the patients, premedication will be done with the antihistamine (H1 and H2) and ALRA. In case of a mild reaction, antihistamines will be administered, and in case of intermediate and severe reactions, intramuscular epinephrine, Prednisolone and Salbutamol will be added. The interval between escalating doses is 4 hours. In case of a mild, moderate and severe reactions the phases will be returned to one and two previous phase. Also, to control the possible anaphylactic attack in the maintenance phase, necessary training will be given to the patient or their parents. The sue of egg white will be continued for 6 months at home. After 6 months, the patient will be referred to measure the size of skin prick test (SPT) and the serum level of IgE and IgG4 to egg white and ovomucoid. Additionally, at the end of 6th month, to evaluate the success rate of desensitization, OFC will be done for all patients. The dose table of Egg white in OFC 0.3 CC 1.2 CC 3 CC 4.5 CC 6 CC 7.5 CC Total 30 cc In the patients with an anaphylactic reaction, OFC starting dose will be equal to 0.015cc (1mg egg protein). The dose table of Egg white in Build up 0.1CC 0.2CC 0.4CC 0.8CC 1.5CC 3 CC 4.5CC 6 CC 8CC 12 CC 16CC 20 CC Selecting the starting dose for the Build up phase is based on the OFC reaction .

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The patients referring to Department of Asthma and Allergy in Rasool Akram Hospital and Jahad Clinic with a history of allergic reaction to egg white up to 2 hours after ingestion and positive Skin

Prick test to Egg white The inability to pass the Oral Food Challenge (OFC) according to the protocol of Middleton Book with using pasteurized raw egg white (Produced by Telavang Egg Industries Co.) Exclusion Criteria: Age less than 4 years old History of Cardiovascular diseases use of Beta-Blockers and ACE Severe and Uncontrolled Asthma

Intervention groups

The patients were randomly divided into two groups: egg white and the placebo group. Three phase including an initial dose escalation during 5 days of hospitalization, to continue the use of received dose at home, to increase the dose up to achieve maintenance dose and maintain the dose after 6 months according to the protocol of use of pasteurized raw egg white(produced by Telavang Co.). To escalate the dose in build-up phase, the patients will be hospitalized for 5 days in Rasool Akram Hospital. Obviously, during the hospitalization and the build-up phase, all treatment will be available to manage the possible attack of an anaphylactic reaction.

Main outcome variables

Desensitization; Specific IgE concentration to Egg white; Specific IgG4 concentration to Egg white; The size of Skin Prick Test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180116038387N1**

Registration date: **2018-02-26, 1396/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-26, 1396/12/07**

Update count: **0**

Registration date

2018-02-26, 1396/12/07

Registrant information

Name

Vahid Ghobadi Dana

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6649 3050

Email address

ghobadidana.v@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of oral immunotherapy with egg white for desensitizing the patients with IgE mediated sensitization to egg white and comparison with the control group

Public title

Effectiveness of Oral Immunotherapy in patients with allergy to egg white

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients referring to Department of Asthma and Allergy in Rasool Akram Hospital and Jahad Clinic with a history of allergic reaction to egg white up to 2 hours after ingestion and positive Skin Prick test to Egg white The inability to pass the Oral Food Challenge (OFC) according to the protocol of Middleton Book with using pasteurized raw egg white (Produced by Telavang Egg Industries Co.)

Exclusion criteria:

Age less than 4 years old History of Cardiovascular diseases Use of Beta-Blockers and ACE Severe and Uncontrolled Asthma

Age

From **4 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **14**

More than 1 sample in each individual

Number of samples in each individual: **2**

Serum Samples

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were randomly selected(according to random number table) from patients referred to the Asthma and Allergy Clinic of Rasool Akram Hospital and Allergy Clinic of Jahad .

Blinding (investigator's opinion)

Single blinded

Blinding description

After obtaining informed consent from all the patients to participate in the study, they will not inform about dividing them in groups(Immunotherapy or placebo).

Placebo

Used

Assignment

Parallel

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, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9311568002

Health conditions studied

1

Description of health condition studied

IgE-mediated sensitization to Egg white

ICD-10 code

T78.0

ICD-10 code description

Anaphylactic reaction due to food

2

Description of health condition studied

IgE-mediated sensitization to Egg white

ICD-10 code

T78.1

ICD-10 code description

Other adverse food reactions, not elsewhere classified

Primary outcomes

1

Description

Desensitization

Timepoint

6 months

Method of measurement

Pass the Oral food challenge test after 6 months use of egg white

2

Description

Specific IgE concentration to Egg white

Timepoint

6 months

Method of measurement

Immunocap

3

Description

Specific IgG4 concentration to Egg white

Timepoint

6 months

Method of measurement

ImmunoCAP

4

Description

The size of Skin Prick Test

Timepoint

6 months

Method of measurement

The size of wheal and Flare(mm)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three phase including an initial dose escalation during 5 days of hospitalization, to continue the use of received dose at home, to increase the dose up to achieve maintenance dose and maintain dose after 6 months according to the protocol of use of pasteurized raw egg white(produced by Telavang Co.). To escalate the dose in build-up phase, the patients will be hospitalized for 5 days in Rasool Akram Hospital. Obviously, during the hospitalization and the build-up phase, all treatment will be available to manage the possible attack of an anaphylactic reaction. For the safety of the patients, premedication will be done with the antihistamine (H1 and H2) and ALRA. In case of a mild reaction, antihistamines will be administered, and in case of intermediate and severe reactions, intramuscular epinephrine and Prednisolone and Salbutamol will be added. The interval between escalating doses is 4 hours. In case of a mild, moderate and severe reactions will be returned to one and two previous phases. Also, to control the possible anaphylactic attack in the maintenance phase, necessary training will be given to the patient or their parents.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
 Hazrat Rasoul Akram Hospital, Iran University of Medical Sciences
Full name of responsible person
 Dr Vahid Ghobadi Dana
Street address
 Hazrat Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran
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2

Recruitment center
Name of recruitment center
 Asthma and Allergy Clinic (Jahad)
Full name of responsible person
 Dr Vahid Ghobadi Dana
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 No.66, Shaheed Nazari cross, Aboreyhan Street, Enghelab Street, Tehran
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Web page address
 http://allergyclinic.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
 Iran University of Medical Sciences
Full name of responsible person
 Dr. Kazem Malakooti
Street address
 Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN
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Email
 adminsite@iums.ac.ir
Web page address
 http://vcr.iums.ac.ir/
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
 30
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

2

Sponsor
Name of organization / entity
 Telavang Company
Full name of responsible person
 Telavang Company
Street address
 No. 241, Skandari and Azadi cross, Tehran
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Email
 Info@Telavang.com
Web page address
 http://www.telavang.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Telavang Company
Proportion provided by this source
 20
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
Industry

3

Sponsor

Name of organization / entity

Dr. Vahid Ghobadi Dana

Full name of responsible person

Dr. Vahid Ghobadi Dana

Street address

تهران- خیابان ستارخان- خیابان نیایش- بیمارستان حضرت رسول
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Email

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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

Dr. Vahid Ghobadi Dana

Proportion provided by this source

50

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

Persons

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Vahid Ghobadi Dana

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Vahid Ghobadi Dana

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Vahid Ghobadi Dana

Position

Fellowship

Latest degree

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Other areas of specialty/work

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Email

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Web page address

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The protocol of study, Clinical report and informed consent is available for the allergist and clinical Immunologists, fellowships, and researchers interested in Oral Immunotherapy.

When the data will become available and for how long

one year after publishing the article

To whom data/document is available

Allergist and clinical Immunologists, fellowships, and researchers interested in Oral Immunotherapy.

Under which criteria data/document could be used

Allergist and clinical Immunologists, fellowships, and researchers interested in Oral Immunotherapy and a history of activities in this filed

From where data/document is obtainable

Dr. Vahid Ghobadi Dana Email: drghobadidana@yahoo.com Tel: 00989121859280 Fax: 00982166996651

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

After sending the request and assess the activities of the researcher, the data will be send for the researcher.(about 2 weeks)

Comments