# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 Middelton 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)

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**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 Middelton 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**
۱۴۴۹۶۱۴۵۳۵

**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
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**2**

**Recruitment center**
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**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
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
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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**
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**
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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

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Iran University of Medical Sciences
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Dr. Vahid Ghobadi Dana
**Position**
Fellowship
**Latest degree**
Specialist
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
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**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**