

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Evaluation of double dose wheat tolerance, serum and dermatologic marker changes in prediction of permanent tolerance in patients with wheat anaphylaxis under oral desensitization.

#### Protocol summary

##### Study aim

Tolerance of double maintenance dose and changes in serum and dermal markers in the prediction of permanent tolerance in anaphylaxis to wheat in patient has undergone oral desensitization

##### Design

This is a Internationale pilot study on 20 people who are at least 1 year in maintenance phase of desensitization to wheat

##### Settings and conduct

predictors of tolerance including consumption of double maintenance phase dose of wheat and serum igE and igG4 levels in individuals who have been exposed to wheat for at least 1 year in the maintenance phase of desensitization and whose persistent tolerance is proven by double blind methods

##### Participants/Inclusion and exclusion criteria

All patients with a history of type 1 or anaphylaxis respond to wheat that are under immunotherapy and 1. At least 1 year are treated with maintenance phase 2, At last for 3 months there is no type 1 allergic reaction 3. Do not discontinue the maintenance regimen Exit criteria: 1. Serum before immunotherapy is not available 2 - The prick test has not been performed before immunotherapy 3. Patient has no satisfaction to test

##### Intervention groups

Individuals who have undergone desensitization to wheat and now they are in maintenance phase at least for 1 year

##### Main outcome variables

Independent Variables: changes in serum igE; changes in serum IgG4; variations in the diameter of the skin prick test; tolerance of double dose wheat Dependent variable: permanent tolerance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190612043872N1**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

##### Registration date

2019-07-08, 1398/04/17

##### Registrant information

##### Name

Ali Pourvali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8824 5435

##### Email address

pourvali.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-06, 1398/04/15

##### Expected recruitment end date

2019-11-22, 1398/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of double dose wheat tolerance, serum and dermatologic marker changes in prediction of permanent tolerance in patients with wheat anaphylaxis under oral desensitization.

## Public title

Evaluation of the relationship between anaphylaxis recovery to wheat with tolerance of higher wheat consumption and serum and skin changes in patients undergoing desensitization

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

All patients with a history of type 1 allergy or anaphylaxis to wheat undergoing at least 1 year of maintenance immunotherapy

### Exclusion criteria:

The maintenance diet has been discontinued For the last 3 months, there is a type 1 allergic reaction Serum before immunotherapy is not available

## Age

From 3 years old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In the final challenge of tolerance to wheat, both the participant and clinical caregivers are blind.

## Placebo

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 science

##### Street address

4 floor,block 1,rasoul hospital ,satarkhan st.Tehrann

##### City

Tehran

##### Province

Tehran

##### Postal code

1415613131

##### Approval date

2019-04-21, 1398/02/01

##### Ethics committee reference number

IR.IUMS.FMD.REC.1398.099

## Health conditions studied

### 1

#### Description of health condition studied

Type 1 sensitivity to wheat

#### ICD-10 code

Z91.01

#### ICD-10 code description

Food allergy status

## Primary outcomes

### 1

#### Description

permanent tolerance to wheat

#### Timepoint

1 month of no wheat consumption

#### Method of measurement

oral wheat challenge

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Sensitized patients to wheat under immunotherapy

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

hazrat rasoul hospital

##### Full name of responsible person

Ali Pourvali

##### Street address

hazrar Rasol hospital,Sattarkhan St.

##### City

Tehran

##### Province

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1445613131  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Naserbakht morteza  
**Street address**  
Hazrat Rasoul hospital,Sattarkhan  
**City**  
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+98 21 2241 6435  
**Email**  
a\_pourvali@yahoo.com  
**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**  
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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Ali Pourvali  
**Position**  
sub-specialty resident  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Hazrat Rasol hospital,Sattarkhan St

## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**  
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## Person responsible for updating data

#### Contact

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**Email**

## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **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**

Yes - There is a plan to make this available

### **Data Dictionary**

Yes - There is a plan to make this available

### **Title and more details about the data/document**

Any data on the main outcome or past history can be shared

### **When the data will become available and for how long**

3 to 6 months after article acceptance.

### **To whom data/document is available**

University researchers and academic journals

### **Under which criteria data/document could be used**

Any analysis with the permission of the main researcher to improve treatment is possible

### **From where data/document is obtainable**

By email a researcher a\_pourvali@yahoo.com Or refer to the Department of allergy and Immunology of Rasoul-e-Akram Hospital

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

up to 2 months after data request

### **Comments**