Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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;tolarance 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 1allergy 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.

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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
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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
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
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Other areas of specialty/work
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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