

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Desensitization to wheat and relationship of tolerance in patients with T regulatory and specific IgE levels

Protocol summary

Study aim

Desensitization to wheat in patients with anaphylactic reaction to wheat

Design

Clinical Trial without control group, single and non-randomized. To confirm the diagnosis of wheat allergy, food challenge is performed for all patients.

Settings and conduct

In this interventional study, desensitization of wheat is carried out in patients referred to the Children Medical Center. Skin Prick test is performed with wheat extract. Specific IgE level of the wheat and T regulatory cell are measured. To confirm the diagnosis of wheat allergy, food challenge is performed for all patients. The patients with anaphylactic reaction to wheat were treated with rush method.

Participants/Inclusion and exclusion criteria

Inclusion and exclusion Criteria: Age more than 5 years, A positive history of severe allergy to wheat, A positive specific IgE to wheat, Confirmation of wheat allergy by OFC/Dissatisfaction of the patients or their parents, Viral or bacterial infectious diseases, Unstable or uncontrolled asthma, Use of medications

Intervention groups

Considering the clinical history and adverse reactions developed in OFC, the patients with anaphylactic reaction entered the study. Intervention group were patients with anaphylactic reactions. The patients with anaphylactic reaction were treated with rush methods.

Main outcome variables

Desensitization to wheat, -Complications, -Tolerance to wheat, Prick test Specific IgE to Wheat, T reg cells count

Registration date: **2020-09-22, 1399/07/01**

Registration timing: **retrospective**

Last update: **2020-09-22, 1399/07/01**

Update count: **0**

Registration date

2020-09-22, 1399/07/01

Registrant information

Name

Samin Sharafian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2015-08-23, 1394/06/01

Actual recruitment end date

2018-02-04, 1396/11/15

Trial completion date

2018-02-04, 1396/11/15

Scientific title

Desensitization to wheat and relationship of tolerance in patients with T regulatory and specific IgE levels

Public title

Desensitization to wheat

Purpose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181220042066N1**

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age more than 5 years A positive history of severe wheat allergy (Anaphylaxis) A positive specific IgE to wheat (in vivo or in vitro tests) Confirmation of wheat allergy by a oral food challenge (OFC)

Exclusion criteria:
Dissatisfaction of patients or their parents to perform OFC Viral or bacterial infectious diseases Unstable or uncontrolled asthma in the time of OFC Use of medications in the time of skin prick test (SPT) or DBPCFC

Age
From **5 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **12**
More than 1 sample in each individual
Number of samples in each individual: **2**
Serum samples
Actual sample size reached: **15**

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blvd. , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2017-08-14, 1396/05/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3196

Health conditions studied

1

Description of health condition studied

Wheat Allergy, Anaphylaxis, Food Allergy

ICD-10 code

T78.0

ICD-10 code description

Anaphylactic reaction due to food

Primary outcomes

1

Description

1- Evaluation of desensitization to wheat

Timepoint

Evaluation of desensitization to wheat after 12 months after Immunotherapy

Method of measurement

1- Skin Prick Test, 2- Specific IgE measurement, 3-clinical symptoms and oral food challenge

2

Description

2-Evaluation of tolerance to wheat

Timepoint

Evaluation of tolerance to wheat after use of free wheat products for two weeks

Method of measurement

clinical symptoms and oral food challenge

Secondary outcomes

1

Description

percentage of T regulatory cells

Timepoint

Before and after Immunotherapy

Method of measurement

Flowcytometry

2

Description

Wheal and flare in Skin Prick Test

Timepoint

Before and after Immunotherapy

Method of measurement

observation of wheal and flare

3

Description

Specific IgE level to wheat

Timepoint

Before and after Immunotherapy
Method of measurement
Immunoblotting test Allergy screen

4

Description

Complications

Timepoint

Before and after Immunotherapy

Method of measurement

examination and observation of clinical symptoms

Intervention groups

1

Description

Intervention group : Patients with anaphylactic reactions to wheat underwent with Rush Method. Patients underwent the premedication with Cetirizine and Montelukast for three days. Then, they were admitted to spend the early phase of rush oral immunotherapy in the department of allergy and immunology. The treatment protocol has a buildup phase and a maintenance phase. The early dose is determined based on the result of oral food challenge. In the rush method, the specific amount of sandwich bread (Senan company) containing known content of wheat protein was given to the patient twice a day. In the case of tolerance and lack of severe symptoms, the amount of bread increased to reach the amount 5.2 grams of wheat protein (equivalent to 52 grams of sandwich bread). The next dose of wheat was determined based on the severity of the symptoms appearing in the previous dose. In the case of mild symptoms, the dose is gradually increased to reach a dose of 5.2 grams of wheat protein, and if moderate symptoms appear, increasing the dose is stopped. This phase was followed by maintenance phase for three months. In the maintenance phase, after increasing dose and consumption of 52 grams Senan sandwich bread, patients should consume this amount of bread daily for up to 3 months. During this period, patients should follow a wheat-free diet in addition to therapeutic doses. After the maintenance period, patients are allowed to gradually use of other foods containing wheat, and in the absence of symptoms, consume products containing wheat, freely. They should not stop consuming the wheat and should consume at least 5.2 grams of wheat protein daily.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center

Full name of responsible person

Samin Sharafian

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Dr. Gharib Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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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

Tehran University of Medical Sciences

Proportion provided by this source

80

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

Tehran University of Medical Sciences

Full name of responsible person

Samin Sharafian

Position

Fellow in training (Allergy and Clinical Immunology)

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoud Movahedi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Fellow in training (Allergy and clinical Immunology)

Latest degree

Specialist

Other areas of specialty/work

Immunology

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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

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 new protocol of immunotherapy for wheat, informed consent and clinical reports of patients, and the results obtained in this study will be provided for sub-specialists in Allergy and Clinical Immunology and researchers after the publication of the article.

When the data will become available and for how long

After article publication

To whom data/document is available

Sub-specialists in Allergy and clinical Immunology in academic hospitals and centers

Under which criteria data/document could be used

Sub-specialists in Allergy and clinical Immunology in academic hospitals and centers

From where data/document is obtainable

Dr. Samin Sharafian Tel: 00989113782097 Email:
samin.sh2020@yahoo.com

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

After submitting a request by the applicant, his resume on wheat Immunotherapy will be reviewed. After consulting and approval of the professors, the data and protocols will be sent to them within a month.

Comments