

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of efficacy and safety of wheat oral immunotherapy in patient with wheat allergy

Protocol summary

Summary

The purpose of this study is oral desensitization therapy of 15 patients with wheat allergy. The study population are the patients above 5 years with IgE-mediated wheat allergy (positive skin prick test to wheat flour extract and wheat specific IgE level above 0.35 IU/L) who don't have severe asthma, chronic urticaria and other severe systemic disease. According to patient's history and their symptoms that occur during double-blind placebo-controlled food challenge test, the patients are divided into two groups with anaphylaxis and without anaphylaxis. We perform Rush Oral Immunotherapy (ROIT) for anaphylactic type and outpatient method for non-anaphylactic type of wheat allergy. Our protocol is consisting of initial build up phase following maintenance phase. Maximum dose during build up phase is 5.2 g wheat protein. We use bread for OIT. In ROIT the patients hospitalize and build up phase perform during several days but in outpatient method the amount of ingestion gradually increase to 52 g of bread (containing 5.2 g wheat protein) within several weeks. After completion the buildup phase, the patients are asked to ingest the maintenance dose (52 g of bread) "daily" for 3 months. In both groups if they are able to take wheat products without adverse reactions for 3 months, they receive confirmed OFC with 5.2 g wheat protein. If this challenge is negative, we regard them as desensitized state and they can ingest wheat products freely without interruption.

General information

Acronym

Wheat Oral Immunotherapy

IRCT registration information

IRCT registration number: **IRCT201204199510N1**

Registration date: **2014-02-26, 1392/12/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-26, 1392/12/07

Registrant information

Name

Alireza Khayatzaadeh

Name of organization / entity

Department of Allergy and Clinical Immunology,
Children's Medical Center at Tehran University of Med

Country

Iran (Islamic Republic of)

Phone

+98 61472153

Email address

a-khayatzadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of wheat oral immunotherapy in patient with wheat allergy

Public title

Wheat oral desensitization in patient with wheat allergy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients above 5 years with IgE mediated wheat allergy (positive skin prick test response to wheat flour and wheat specific IgE level above 0.35 IU/L); positive oral food challenge to wheat. exclusion criteria: severe and uncontrolled asthma; chronic urticaria; significant systemic disease; poor compliance

Age

From **5 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **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

Tehran University of Medical Sciences

Street address

Office of TUMS Public Relations, sixth Floor, Ghods street, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2012-12-31, 1391/10/11

Ethics committee reference number

91/d/130/2505

Health conditions studied

1

Description of health condition studied

wheat allergy

ICD-10 code

T78

ICD-10 code description

Adverse effects, not elsewhere classified

2

Description of health condition studied

Desensitization

ICD-10 code

Z51.6

ICD-10 code description

Desensitization to allergens

Primary outcomes

1

Description

Daily consumption of wheat products without any complications

Timepoint

Before oral immunotherapy and 3 month after starting maintenance phase

Method of measurement

Oral food challenge with 52 gr of bread containing 5.2 g wheat protein

Secondary outcomes

1

Description

Evaluation of skin, respiratory, gastrointestinal symptoms and anaphylaxis reaction during course of treatment

Timepoint

During buildup and maintenance phase

Method of measurement

Number of participants with adverse events and observation of their sign and symptoms

Intervention groups

1

Description

The anaphylactic patients take Loratadine and Montelukast, three days prior to admission to prevent the severe adverse reaction. On the first day of admission; we perform OFC again with premedication, so we determine the initial dose of rush OIT. In rush phase, patients take bread two time a day, and if they can take them without severe reactions, they are asked to take bread with 50% increase of the former dose. Maximum amount of bread is set at 52 g of bread. In outpatient method after the OFC, the patients are asked to ingest a small amount of wheat at home every day. The initial protein dose is about 1/4 of the threshold to elicit positive symptoms in OFC without premedication. Amount of wheat ingestion gradually buildup to 52 g of bread that contain 5.2g of wheat protein according to their symptoms. In both groups after completion of build-up phase, the patients are asked to ingest 52 g of bread containing 5.2 g wheat protein as a maintenance dose "daily" for 3 months. During this period the patients should continue the wheat-elimination diet. At the end of

maintenance phase we performed OFC with 52 g of bread (containing 5.2 g wheat protein). If the patients could pass the test, we regarded them as desensitized, and after that they could ingest wheat products without any restrictions. The patients who completed treatment had to eat at least 5.2 g wheat protein every day since we were not sure whether they have got tolerance or not. Moreover it is not difficult for most of people to eat 5.2 g wheat protein per day, because they usually have the same amount of wheat products in their daily diet.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children's Medical Center Hospital

Full name of responsible person

Alireza Khayat-zadeh

Street address

Children' Medical Center, Dr.Gharib st, Keshavarz Blvd, Tehran 14194, I.R. of Iran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Office of TUMS Public Relations, sixth Floor, Ghods St., Keshavarz Blvd. Vali-e-Asr Ave., Tehran, Iran.

City

Tehran

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

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Department of Allergy and Clinical Immunology in Children's Medical Center at Tehran University of M

Full name of responsible person

Alireza Khayat-zadeh

Position

Fellow of allergy and clinical immunology

Other areas of specialty/work**Street address**

Children' Medical Center, Dr.Gharib st, Keshavarz Blvd, Tehran 14194, I.R. of Iran

City

Tehran

Postal code**Phone**

+98 21 6147 2153

Fax**Email**

a-khayatzadeh@razi.tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Allergy and Clinical Immunology of Children's Medical Center at Tehran University of M

Full name of responsible person

Masoud Movahedi

Position

Associate Professor

Other areas of specialty/work**Street address**

Children' Medical Center, Dr.Gharib st, Keshavarz Blvd, Tehran 14194, I.R. of Iran

City

Tehran

Postal code**Phone**

+98 21 6147 2153

Fax**Email**

movahedm@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Department of Allergy and Clinical Immunology of Children's Medical Center at Tehran University of M

Full name of responsible person

Alireza Khayat-zadeh

Position

Fellow of allergy and clinical immunology

Other areas of specialty/work**Street address**

Children' Medical Center, Dr.Gharib st, Keshavarz

Blvd, Tehran 14194, I.R. of Iran

City

Tehran

Postal code

Phone

+98 21 6147 2153

Fax

Email

a-khayatzadeh@razi.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty