

# 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

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Children's Medical Center at Tehran University of Med

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Iran (Islamic Republic of)

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##### 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

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

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

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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**

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**Position**

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**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*