

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effective Desensitization to wheat, for Allergy with Wheat in 2-18 years old cases for 1 year in Allergy and Immunology clinic in Rasul Akram hospital

Protocol summary

Summary

Effective Desensitization to wheat for allergy with Wheat in cases 2-18 age for 1 year in Allergy and Immunology clinic in Rasul Akram hospital. Inclusion criteria: 1- patients with type one hypersensitivity reaction to wheat. 2-patients age ranging from 2-18 years old. 3- patients without cardiac diseases (heart failure, heart valve insufficiency, severe valve stenosis, myocardial infarction). 4-patients without severe pulmonary diseases (severe asthma, chronic obstructive pulmonary disease, severe chronic bronchiolitis). 5-informed consent was taken for including the patient in the study. 6- Not having any other chronic disease. Exclusion criteria: 1-patients who did not permit us to enter them in the study. 2- patients with hypersensitivity reactions other than type one reaction. 3-patients having cardiac diseases (heart failure, heart valve insufficiency, severe valve stenosis, myocardial infarction) 4- patients with severe pulmonary diseases (severe asthma, chronic obstructive pulmonary disease, severe chronic bronchiolitis). 5-patients age less than 2 or more than 18 years old. There are 5 patients entering our study, for whom skin prick testing, serum total and specific IgE level, complete blood cell count and nasal smear was done before and after protocol. Desensitization protocol was started with small doses of dose semolina flour and the dose was increased slowly during seven months until reaching total dose of 4.5 grams of semolina powder, and then desensitization was continued with pasta from one piece of pasta per day to 100 pieces of pasta (60 grams) per day. During the study patient stays under allergy subspecialist observe and in the hospital and stays in the hospital until 2 hours after desensitization in every session, and resuscitation equipment is available during desensitization. if patient develops severe allergic reactions during desensitization (respiratory distress, severe dyspnea, systolic hypotension more than 30% from baseline or less than

90 mmHg, cardiac arrhythmia, generalized urticarial or anaphylactic reaction, desensitization will be discontinued. If patient tolerates the desensitization protocol or just develops mild reactions such as urticarial, skin rash, mild wheezing, or weakness and ... the patient will continue the desensitization protocol and during 4 months patient will tolerate maximum semolina flour dose and enters the second course of desensitization. In the second course, we start from pasta (wheat flour) from small doses and during 7 months the dose will reach maximal dose of 100 pieces of pasta. there are 5 patient who enter the protocol. major goals: taking any amount of wheat in patients. Minor goals: to determine serum total IgE level in patients with sensitivity to wheat flour before desensitization, 2-determination of serum total IgE levels in patients after beginning of desensitization. 3- determination of eosinophilia in CBC of patients before desensitization.4- determination of eosinophilia in CBC of patients after desensitization.5-determination of skin prick testing results in patients before desensitization.6- determination of skin prick testing results in patients after desensitization 7- determination of nasal smear results before desensitization. 8- Determination of nasal smear results after desensitization. Clinical purposes: 1- making tolerance in taking wheat flour in patients with immediate type hypersensitivity reactions (type1) and prevention from anaphylactic reactions. 2-improving quality of life and eliminating limitations in nutrition in patients with immediate type hypersensitivity reactions (type1). Major variables: allergy and reaction to wheat in patients. Secondary variables: blood eosinophilia, nasal smear eosinophilia, serum total IgE levels, serum wheat specific IgE levels, skin prick test.

General information

Acronym

food allergy

IRCT registration information

IRCT registration number: **IRCT2013102015076N1**

Registration date: **2014-06-07, 1393/03/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-07, 1393/03/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effecttive Desensitization to wheat, for Allergy with Wheat in 2-18 years old cases for 1 year in Allergy and Immunology clinic in Rasul Akram hospital

Public title

Desensitization wheat

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with type1 allergic reaction to wheat flour; age between 2-18 years old; normal physical examination; no sever asthma; no cardiac diseases, no other chronic diseases and informed consent was taken from patients. Exclusion criteria: 1-patients who did not permit us to enter them in the study. 2-patients with hypersensitivity reactions other than type one reaction. 3-patients having cardiac diseases (heart failure, heart valve insufficiency, severe valve stenosis, myocardial infarction) 4- patients with severe pulmonary diseases (severe asthma, chronic obstructive pulmonary disease, severe chronic bronchiolitis). 5-patients age less than 2 or more than 18 years old.

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **5**

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

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemat highway

City

Tehran

Postal code

Approval date

2014-04-29, 1393/02/09

Ethics committee reference number

496/105/93/5

Health conditions studied

1

Description of health condition studied

Food allergy

ICD-10 code

T78.1

ICD-10 code description

Other adverse food reactions, not elsewhere classified

Primary outcomes

1

Description

desentization with wheat

Timepoint

no urtrica in examination.no asthma ,no eczema

Method of measurement

physician examination and parent

Secondary outcomes

1

Description

eosinophilia

Timepoint

befor and after portocol

Method of measurement

see cbcdiff

2

Description

prick test

Timepoint

befor &after portocol

Method of measurement

study and see wheal

3

Description

eosinophilia in nasal smear

Timepoint

befor and after portocol desentization

Method of measurement

see in nasal smear

4

Description

IgE level in serum

Timepoint

befor and after portocol desentization

Method of measurement

elisia

5

Description

wheat spcific IgE level in serum

Timepoint

befor and after portocol desentization

Method of measurement

elisia

Intervention groups

1

Description

desentization wheat pation with allergy type1

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Rasol Akram Hospital

Full name of responsible person

Dr Mahsa Rekabi

Street address

Rasol Akram Hospital , Niayesh st., Sattar Khan st.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Grant name

93/105/496/3

Grant code / Reference number

93/105/496/3

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

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

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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