Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

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

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
Name
Mahsa Rekabi
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6655 4933
Email address
mahsarekabi1@gmail.com

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 diseas, 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/د

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
desentizition 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
desentiziation 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.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Ms. Cheshmi
Street address
Iran University of Medical Sciences, Hemat highway
City
Tehran
Grant name
93/105/496/د
Grant code / Reference number
93/105/496/د
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

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Mahsa Rekabi
Position
MD, fellowship of pediatic asthma & allergy
Other areas of specialty/work
Street address
Rasol Akram Hospital , Niayesh st., Sattar Khan st.
City
Tehran
Postal code
1445613131

Phone
+98 21 6655 4933
Fax
+98 21 6655 4933
Email
mahsarekabi1@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Mohamad Nabavi
Position
Assistant professor
Other areas of specialty/work
Street address
Rasol Akram Hospital , Niayesh st., Sattar Khan st.
City
Tehran
Postal code
1445613131
Phone
+98 21 6655 4933
Fax
+98 21 6655 4933
Email
www.nabavi.m.iums.ir.ac.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Mahsa Rekabi
Position
MD, fellowship of pediatic asthma & allergy
Other areas of specialty/work
Street address
Rasol Akram Hospital , Niayesh st., Sattar Khan st.
City
tehran
Postal code
1445613131
Phone
+98 21 6655 4933
Fax
+98 21 6655 4933
Email
mahsarekabi1@gmail.com
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