

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of oral immunotherapy with cows milk in desensitization and induce tolerance in patients with cows milk allergy

Protocol summary

Summary

In this study, patients over 3 years with TYPE 1 HYPERSENSITIVITY which Has been confirmed based on history ;physical exam . skin test ,immunocap.and double blind placebo control challenge test, have been considered for cow's milk oral immunotherapy with Specific Protocols. We do immunotherapy According to the patients history and positive result of DBPCFC ; The study consisted of three phases : rash and climbing and maintenance. This study have been done on an outpatient basis at the hospital. amount of milk be given to patients slowly until a dose of 200-250 mL within a few weeks. Patients eat 200 to 250 ml of milk for 3 months After completion of the ascending phase (maintenance phase). If Patients able to eat milk products without adverse reaction for one year the food challenge test (OFC) is done to check the status of tolerance Once again. So that consumption of milk Stops for 2 weeks and OFC tests are done for patients. If the challenge test was positive means that not created tolerance in patients,they have been desensitization and Should consume milk daily. If the challenge test was negative means that created tolerance in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041621793N1**

Registration date: **2015-06-15, 1394/03/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-15, 1394/03/25

Registrant information

Name

Mohsen Ebrahimi

Name of organization / entity

Tehran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral immunotherapy with cows milk in desensitization and induce tolerance in patients with cows milk allergy

Public title

Effect of oral immunotherapy in improving Sensitivity in Patients with cow's milk Allergy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:patients above 3 years old with IgE mediated cow's milk allergy which confirm challenge test
exclusion criteria:lack of parental and patient consent,non IgE mediated allergy to cows milk and

uncontrolled severe asthma.

Age
From **3 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **14**

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
Children Medical Center, Keshavarz Blvd, Dr Gharib
St, Tehran, IR Iran

City
Tehran

Postal code
1417653761

Approval date
2015-03-04, 1393/12/13

Ethics committee reference number
6211568003-140288

Health conditions studied

1

Description of health condition studied
Food allergies

ICD-10 code
T78.0

ICD-10 code description
Anaphylactic shock following adverse reactions Food

Primary outcomes

1

Description
Create tolerance to cow's milk

Timepoint
One year after the end of intervention

Method of measurement
clinical signs and open food challenge test

2

Description
Desensitization to cow's milk

Timepoint
6 months after starting intervention

Method of measurement
Based on clinical signs

Secondary outcomes

1

Description
Changes in the level of specific IgE

Timepoint
before starting intervention and six months after the end
of intervention

Method of measurement
RIDA test

2

Description
Changes in skin test before and after desensitization

Timepoint
before starting intervention and 6 months after the end
of the intervention

Method of measurement
Skin Prick Test

Intervention groups

1

Description
In this study,A certain amount of milk are given to
patients under medical supervision and a half hours to
be considered.the desensitization beginning with 0.1mL
of cow's milk, and increasing the dosage weekly(For 10
to 12 weeks) until to reaching a dose of 200 mL of milk.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Childrens Medical Center

Full name of responsible person
Mohsen Ebrahimi

Street address

Children Medical Center, Keshavarz Blvd, Dr Gharib
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City

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

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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

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**

Childrens Medical Center

Full name of responsible person

Mohsen Ebrahimi

Position

Allergy and Immunology Fellowship

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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