

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effect of oral desensitization in patients with acute allergy to cow milk based on Prik skin test

Protocol summary

Summary

study target: Investigating the effect of oral desensitization in patients with acute allergy to cow milk based on Prick skin test study design: clinical trial with no control group, before after compare Main inclusion criteria: Patients with sever IgE mediated hypersensitivity reactions to Cow's Milk which weren't improved over 2 years of age main exclusion criteria: Uncontrolled asthma; Cardiovascular disease or other significant systemic disease; Patients having poor compliance sample size: at least 18 person intervention: oral desensitization to cow milk duration of intervention: in 6 month, weekly primary outcomes: Prik skin test, Anti milk IgE

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080814305N1**

Registration date: **2014-02-12, 1392/11/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-12, 1392/11/23

Registrant information

Name

Delara Babaie

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

dbabaie@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Mofid children's Hospital, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-05-01, 1392/02/11

Expected recruitment end date

2014-12-01, 1393/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of oral desensitization in patients with acute allergy to cow milk based on Prik skin test

Public title

Investigating the effect of oral desensitization in patients with acute allergy to cow milk based on Prik skin test

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with sever IgE mediated hypersensitivity reactions to Cow's Milk which weren't improved over 3 years of age; Immediate reaction in open oral cow's milk challenge; • Diet free from milk and milk products Exclusion Criteria: Uncontrolled asthma; Cardiovascular disease or other significant systemic disease; Patients having poor compliance

Age

From **3 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: **18**

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
Mofid research excellence center

Street address
Shariati, Mofid children's hospital

City
Tehran

Postal code

Approval date
2014-12-24, 1393/10/03

Ethics committee reference number
1392-1-119-1186

Health conditions studied

1

Description of health condition studied
cow's Milk allergy

ICD-10 code
T78.0

ICD-10 code description
Anaphylactic shock due to adverse food reaction

Primary outcomes

1

Description
Prik skin test

Timepoint
begining of study, month 6

Method of measurement
observation of redness of aleren contact areaa, itching

2

Description
Anti cow's milk IgE

Timepoint
begining of study, month 6

Method of measurement
titration of IgE, Eliza

Secondary outcomes

empty

Intervention groups

1

Description
Fifteen children over 3 year with history of anaphylaxis to cow's milk, positive skin prick test (SPT), and positive oral food challenge were recruited. Skin prick test with Milk extract, full dilution and different dilutions of milk, depends on patient's reaction was performed for all the patients. The dilution of milk which induced 3-5 mm of wheal was selected as a stating dilution. Then it started form 2 drop of the dilution and increased according the protocol. The dose was increased weekly to achieve an intake of 120 mL in approximately 4 months. All doses were administered under medical supervision in a clinical setting. After receiving the dose, children were carefully assessed for positive reactions. In the cases of anaphylaxis the dose returned to the last tolerated dose for one week, then it was increased slower

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid children's Hospital

Full name of responsible person
Delara Babaie

Street address
Dep. of allergy , Mofid children's Hospital , Shariati St.

City
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2

Recruitment center

Name of recruitment center
Rasool hospital

Full name of responsible person
Morteza fallahpour

Street address
Dep. of allergy and clinical immunology, rasool hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mofid research excellence center

Full name of responsible person

Fatemeh Gorji

Street address

Mofid children's hospital

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mofid research excellence center

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Delara Babaie

Position

Assistant professor of Allergy and Clinical Immunology

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

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Person responsible for updating data

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Morteza fallahpour

Position

Fellow of Allergy and Clinical Immunology

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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