Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effect of oral desensitization in patients with acute alergy 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 least18 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)

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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 alergy to cow milk based on Prik skin test

Public title

Investigating the effect of oral desensitization in patients with acute alergy 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 challange;• 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

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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

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Dep. of allergy and clinical immunology, rasool hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mofid research excellence center
Full name of responsible person
Fatemeh Gorji
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Mofid children's hospital
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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

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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