Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effect of oral immunotherapy with cow's milk products and conventional desensitization in children with allergy to heated cow's milk: a clinical trial

Protocol summary

Study aim
desensitization in patients with cow milk allergy

Design
Triple-blind randomized placebo controlled clinical trial, community based, two parallel group design with 25 patients suffering from type 1 hypersensitivity

Settings and conduct
In the allergy and immunology clinic patients were randomized into milk and muffins groups. for all patients before and after desensitization skin prick test, IgE serum level test, the eosinophil and T regulatory cell counting were performed. The study is triple-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients two years and older; presentation of skin symptoms such as urticaria, erythema and angioedem; gastrointestinal symptoms such as severe vomiting, abdominal pain and diarrhea; respiratory symptoms such as rhinitis and bronchospasm; these symptoms should be present up to two hours after exposure; these symptoms should be present at least in last six months; positive skin prick test for cow's milk or measurement of sIgE for cow's milk Exclusion criteria:cellular immune response that it's not mediated by IgE; malignancy or severe immunodeficiency disorders; using beta blockers; uncontrolled severe persistent asthma; Cardiovascular disease that epinephrine administration in them is contraindicated; Taking immunosuppressive drugs; Eosinophilic Gastrointestinal; Disorder that produced by the milk and it diagnosed

Intervention groups
In the intervention, 12 patients (2 female and 10 male) used heated cow milk (muffin). In control group, 13 patients (5 female and 8 male) underwent oral immunotherapy with cow milk.

Main outcome variables
Regulatory T cell; Specific IGE for milk; Milk Desensitization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170426033658N2**
Registration date: **2018-04-01, 1397/01/12**
Registration timing: **retrospective**

Last update: **2018-04-01, 1397/01/12**
Update count: **0**

Registration date
2018-04-01, 1397/01/12

Registrant information

Name
Emad Bahraminiya

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research , Tehran University of Medical Sciences

Expected recruitment start date
2016-04-29, 1395/02/10

Expected recruitment end date
2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral immunotherapy with cow's milk products and conventional desensitization in children with allergy to heated cow's milk: a clinical trial

Public title

clinical trial of the effect of raw and cooked milk immunotherapy in children with milk allergy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients two years and older Presentation of skin symptoms such as urticaria, erythema and angioedema gastrointestinal symptoms such as severe vomiting, abdominal pain and diarrhea respiratory symptoms such as rhinitis and bronchospasm Presentation of the symptoms up to two hours after exposure these symptoms should be present at least in last six months positive skin prick test for cow's milk or measurement of sIgE for cow's milk positive challenge test with cow's milk

Exclusion criteria:

cellular immune response that is not mediated by IgE malignancy or severe immunodeficiency disorders using beta blockers uncontrolled severe persistent asthma Cardiovascular disease that epinephrine administration is contraindicated in them Taking immunosuppressive drugs previously diagnosed Eosinophilic Gastrointestinal Disorder in response to milk

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of simple randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

1- participants, 2- Physicians, and nurses, who care for participants, 3- data analyser

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Siences, Poorsina ave, Gods ave, Enghelab street

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2016-11-22, 1395/09/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1076

Health conditions studied

1

Description of health condition studied

food allergy

ICD-10 code

T78.4

ICD-10 code description

Allergy, unspecified

Primary outcomes

1

Description

regulatory T cell

Timepoint

Before intervention, after intervention

Method of measurement

Flow cytometry

2

Description

Specific IGE for milk

Timepoint

Before intervention, after intervention

Method of measurement

RIDA

3

Description

Milk Desensitization

Timepoint

Before intervention, after intervention

Method of measurement

Clinical

Secondary outcomes

1

Description

symptoms,anaphylaxis,desensitization

Timepoint

Immediately after intervention.

Method of measurement

physical examination

Intervention groups

1

Description

In the intervention group, certain amount of muffin is given to patients and they are monitored for 4 hours under medical observation. Then desensitization with 1.8 muffin's slice is initiated and the dosage will be added monthly (For 4 to 6 months) until it reaches one complete muffin.

Category

Other

2

Description

In the control group, certain amount of milk is given to patients and they are monitored for half an hour under medical observation. the desensitization is initiated with 0.1mL of cow's milk and the dosage will be added weekly (For 10 to 12 weeks) until it reaches the amount of 200 cc.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center Hospital

Full name of responsible person

Dr.Emad Bahraminiya

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No. 62, Qarib St, Keshavarz Blvd,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Masood Yunesian

Street address

Sixth floor,Central Organization of Tehran University,Qods street,Keshavarz Blvd

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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

Vice chancellor for Research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Emad Bahraminiya

Position

fellowship of allergy and clinical immunology

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Dr.Masoud Movahedi
Position
Full Professor
Latest degree
Subspecialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
IPD collected for the primary outcome measure only
When the data will become available and for how long
starting 2 months after publication
To whom data/document is available
people working in academic institutions and clinical immunology specialist
Under which criteria data/document could be used
use of data for systematic review articles
From where data/document is obtainable
email address: bahraminiya.emad@gmail.com
What processes are involved for a request to access data/document
Just ask for an email and send it within less than a week.
Comments