

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The assessment of specificity of Double Dose Oral Food Challenge in predicting of permanent tolerance development in patient with history of anaphylaxis to cows milk under subject of desensitization

Protocol summary

Study aim

evaluation of usefulness of Double Dose Oral Food Challenge plus Specific IgE & IgG4 and size of weal in prick and prick to prick test in prediction of permanent tolerance development in cow`s milk anaphylaxis whome underwent desensitization.

Design

in this study, 22 patient with a history to anaphylaxis to cows milk protein that underwent desensitization and fulfill the inclusion criteria will recruit to Allergic clinic of Rasoul e Akram hospital and will be tested with Specific IgE & IgG4 , prick and prick to prick and Double Dose Oral food challenge test, then all of them will be strict avoided of cow`s milk for 3 weeks and after that standard oral food challenge will be done again.

Settings and conduct

patient with a history of anaphylaxia to cows milk protein under the subject of desensitization that refer to Rasool Allergic clinic

Participants/Inclusion and exclusion criteria

The patient with a history of anaphylaxis to cows milk allergy under subject to desensitization, 24 months after desensitization and history of any symptoms during the last 3 months, and consent to participate to project.

Intervention groups

there is no control group. all the permanent patients with anaphylaxis to cows milk whom underwent desensitization and eligible inaccording to inclusion criteria, will be assessed by: assessment of Specific IgE & IgG4 , prick and prick to prick and Double Dose Oral food challenge test, then all of them will be strict avoided of cow`s milk for 3 weeks and after that standard oral food challenge will be done again.

Main outcome variables

Permanent tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181230042174N2**

Registration date: **2019-08-04, 1398/05/13**

Registration timing: **prospective**

Last update: **2019-08-04, 1398/05/13**

Update count: **0**

Registration date

2019-08-04, 1398/05/13

Registrant information

Name

morteza fallahpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 4933

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-08, 1398/05/17

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of specificity of Double Dose Oral Food Challenge in predicting of permanent tolerance development in patient with history of anaphylaxis to cows milk under subject of desensitization

Public title

The assessment of ability of Double Dose Oral Food Challenge in predicting the permanent tolerance development in patient with history of anaphylaxis to cows milk under subject of desensitization

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

History of anaphylaxis to cows milk protein at least 24 months post desensitization symptom free within last 3 months consent to project

Exclusion criteria:

every body who has not fulfill inclusion criteria not full adherence to protocol of this study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 22

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

Ethics committee of Iran university of medical science

Street address

sattarkhan Ave, Mazyar mansoori Ave, Rasool Akram hospital

City

Tehran

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Postal code

۱۴۴۵۶۱۳۱۳۱

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.IUMS.FMD.REC.1397.333

Health conditions studied

1

Description of health condition studied

Cows milk protein allergy

ICD-10 code

T78.0

ICD-10 code description

Anaphylactic reaction due to food

Primary outcomes

1

Description

slgE level

Timepoint

before the desensitization and during project

Method of measurement

serum sample

2

Description

slgG4 level

Timepoint

before the desensitization and during project

Method of measurement

serum sample

3

Description

double dose OFC

Timepoint

before cessation of using food for 3 weeks

Method of measurement

oral food challenge

4

Description

skin prick tests

Timepoint

before the desensitization and during project

Method of measurement

measuring the wheal and erythem

5

Description

standard oral food challenge

Timepoint

after 3 week avoidance of cow`s milk

Method of measurement

standard oral food challenge

Secondary outcomes

1

Description

permanent tolerance

Timepoint

at least 24 months after desensitization

Method of measurement

Specific IgE & IgG4 , prick and prick to prick and Double Dose Oral food challenge test, then all of them will be strict avoided of cow`s milk for 3 weeks and after that standard oral food challenge will be done again.

Intervention groups

1

Description

there is no control group. all the permanent patients with anaphylaxis to cows milk whom underwent desensitization and eligible in according to inclusion criteria, will be assessed by: assessment of Specific IgE & IgG4 , prick and prick to prick and Double Dose Oral food challenge test, then all of them will be strict avoided of cow`s milk for 3 weeks and after that standard oral food challenge will be done again. at first 2 cc of blood serum will be stored at -21 c freezer and after finishing the sampling they will be assessed with immuno-CAP for sIgE & sIgG4. in the next step skin prick test with Greer allergy extracts and and prick to prick test with fresh milk will be done. oral food challenge will done with 8 gram protein equal with 72 g aptamil formula with cow`s milk base in 100 cc water( recommended daily dose in desensitization period was 4 g protein equal to 36g aptamil powder in 100 cc water). liquid will be use each 20 minutes with amount of:1,4,10,20,25 and 25 ml, then all the patients will be avoided of cow`s milk for 3 weeks and after that standard OFC will be repeated with 4 g protein in 100 cc .individuals who passed the second OFC will be considered permanent tolerance. all the data will analyses.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

rasool akram allergy clinic

Full name of responsible person

Fatemeh Alizadeh

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niyayesh Ave. rasool akram hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Morteza Naserbakht

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East Hemmat Highway. Iran Medical University

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Morteza Fallahpour

Position

associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

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Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available