Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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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, Maziyar mansoori Ave, Rasool Akram hospital
City
Tehran
Province
Tehran
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
sIgE level
Timepoint
before the desensitization and during project
Method of measurement
serum sample

2

Description
sIgG4 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 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. 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
Street address
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
Street address
East Hemmat Highway. Iran Medical University
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Email
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Web page address
http://hrmc.iums.ac.ir/
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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Morteza Fallahpour

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Latest degree

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Other areas of specialty/work

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Email

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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