Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A multi-centers Non-inferiority clinical trials for evaluating the efficacy of inhalant and food allergic extracts made from domestic sources by skin prick testing in comparison of their matched commercial extracts on a group of patients with history of allergic diseases visiting allergy clinics

Protocol summary

Study aim

Comparison of the efficacy of domestic extracts and their matched commercial extracts in skin prick testing
Comparison of the sensitivity of domestic extracts and their matched commercial extracts in skin prick testing
Comparison of the specificity of domestic extracts and their matched commercial extracts in skin prick testing
Comparison of the side effects of domestic extracts and their matched commercial extracts in skin prick testing

Design

A non-inferiority clinical trial with parallel group , no randomized, not blinded, , phase 2 , on 102 patients with history of allergy

Settings and conduct

This trial will conducted in several allergy clinics in different cities including Birjand, Shiraz and Mashhad. Allergic patients who are candidate for skin prick testing will be informed about the aims of the study and after their approval for participating in the study and receiving consent form, skin prick test will be performed with commercial allergenic extracts and the results will be recorded. After that, skin prick test will be performed with 5 to 10 of matched domestic extracts on the patient's other hand and the results will be recorded as well. The result of skin reactivity to commercial and domestic extracts as well as immediate and late (during the first 24 hours) side effects for both extracts will be evaluated and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of respiratory or food allergy
Exclusion criteria: History of anaphylaxis or uncontrolled asthma

Intervention groups

Patients with history of respiratory or food allergy who should perform skin prick test with commercial extracts will tested with matched domestic extracts as well

Main outcome variables

positive skin reaction; Negative skin reaction, side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181216042006N1**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **prospective**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name
Mohammad Fereidouni
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 56 3243 3004
Email address
dr.m.fereidouni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A multi-centers Non-inferiority clinical trials for evaluating the efficacy of inhalant and food allergic extracts made from domestic sources by skin prick testing in comparison of their matched commercial extracts on a group of patients with history of allergic diseases visiting allergy clinics

Public title

Comparison of the efficacy of domestic allergenic extracts with matched commercial imported extracts

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

patients with history of allergy to inhalant or food allergens who visit allergy clinics and are candidate of performing skin prick test by specialist

Exclusion criteria:

Having serious health problems such as cancer, immunodeficiency, autoimmunity, cardiac disease and severe infection Pregnancy or breastfeeding History of anaphylaxis or uncontrolled asthma Current dermatographism or urticaria History of allergy immunotherapy during the last 5 years Using medicine which interfere with skin prick test such as antihistamines, oral corticosteroids, narcotics or sedatives during the last week

Age

From **2 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **107**

More than 1 sample in each individual

Number of samples in each individual: **10**

Up to five food extracts and up to 10 inhalant extracts can be tested in each case

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Ghaffari street

City

Birjand

Province

South Khorasan

Postal code

9717686735

Approval date

2020-03-03, 1398/12/13

Ethics committee reference number

IR.BUMS.REC.1398.376

Health conditions studied

1

Description of health condition studied

Allergic rhinitis

ICD-10 code

J30.1

ICD-10 code description

Allergic rhinitis due to pollen

2

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

3

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

4

Description of health condition studied

Food allergy

ICD-10 code

Z91.01

ICD-10 code description

Food allergy status

Primary outcomes

1

Description
positive skin reactivity to domestic extracts in comparison to commercial extracts
Timepoint
15 minutes after doing skin prick test
Method of measurement
Area of wheal created by extracts in square milometers

Secondary outcomes

1

Description
Side effects of skin prick testing with commercial or domestic extracts including large local reactions or systemic reactions
Timepoint
during the first 24 hours after doing skin prick test
Method of measurement
A design questionnaire

Intervention groups

1

Description
Intervention group: allergic patients who are referred to allergy clinic and are candidate of skin prick test with commercial extracts from Stallergen or Greer Companies. Based on the patient's history and symptoms, skin prick test usually performs with a battery of 20 -30 allergenic extracts from plants' pollen, foods or animals. one drop of each allergenic extracts placed on volar surface of patient's hand and after a small scratch with sterile lancet, the area of wheal and flare recorded after 15 minutes.
Category
Diagnosis

2

Description
Intervention group: allergic patients who are referred to allergy clinic and are candidate of skin prick test and the prick test performed with commercial extracts from Stallergen or Greer Companies, will be tested with domestic extracts on their other hand and after finishing testing with commercial extracts. Based on the patient's history and symptoms, skin prick test usually performs with a battery of 20 -30 allergenic extracts from plants' pollen, foods or animals. one drop of each allergenic extracts placed on volar surface of patient's hand and after a small scratch with sterile lancet, the area of wheal and flare recorded after 15 minutes. After doing skin prick test with commercial extracts and receiving consent form from patients, skin prick test with some of the match domestic extracts will performed on the patient's other hand and the result will be recorded. Domestic extracts were prepared from pollen of some common allergenic plants in Iran as well as food allergens. In case of pollen's extracts, during pollination season, the pollens were collected and with using specific sieves and sedimentation methods, pure pollen achieved and the purity was approved by microscopic evaluation. after that, 1 gram of pure pollen was mixed with 9 milliliters of aqueous buffer for 24 hours and after centrifugation and filtering, total amount of protein in the extracts was measured. In the next step and to evaluate the pattern of allergenic bands in the extracts, SDS-PAGE was performed and finally the sterilization process was done and microbial cultured approved the sterility of the extracts. For stability testing, the extracts were stored either at 37 centigrade degree for 2 months or at 25 centigrade degree for 6 months and after that the quantity and quality of extracts were measured. In case of good stability and sterility the extracts were mixed with equal amount of sterile glycerol and after packaging and labeling will be used for skin prick testing. The result of skin sensitivity and side effects with both commercial and domestic extracts were compared by using proper statistical tests.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized Clinic of Emam Reza Hospital, Birjand University of Medical Sciences
Full name of responsible person
Mohammad Fereidouni
Street address
Taleghani 9 street
City
Birjand
Province
South Khorasan
Postal code
9717686735
Phone
+98 56 3222 2600
Email
htgbirjand@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Tooba Kazemi
Street address
Ghaffari street
City
Birjand

Province
South Khorasan
Postal code
9717686735
Phone
+98 56 3238 1500
Email
htgbirjand@gmail.com
Grant name
Grant code / Reference number
5147
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Fereidouni
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Allergy
Street address
Ghaffari street
City
Birjand
Province
South Khorasan
Postal code
9717686735
Phone
009856323381500
Email
dr.m.fereidouni@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Fereidouni
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Ghaffari street, Birjand Univeristy of Medical Sciences, Birjand, Iran
City
Birjand
Province
South Khorasan
Postal code
9717686735
Phone
+98 56 3243 3004
Fax
Email
dr.m.fereidouni@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Fereidouni
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medicine
Street address
Ghaffari street, Birjand Univeristy of Medical Sciences, Birjand, Iran
City
Birjand
Province
South Khorasan
Postal code
9717686735
Phone
+98 56 3243 3004
Fax
Email
dr.m.fereidouni@gmail.com

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
Yes - There is 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

Title and more details about the data/document

Some data will be released

When the data will become available and for how long

Starting 6 months after publishing the results

To whom data/document is available

Medical universities affiliates

Under which criteria data/document could be used

Will evaluate on demand

From where data/document is obtainable

Responsible person

What processes are involved for a request to access data/document

Written request with including the purpose of request

Comments