Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of rehabilitation (strength and endurance exercises) on respiratory symptoms, lung function indexes and some inflammatory mediators in asthmatic patients.

Protocol summary

Study aim

Effect of strength and endurance exercises on respiratory symptoms, lung function and inflammatory mediators in asthmatic patients.

Design

Intervention is limited to one group of eligible applicants (30 people) without randomization. This study does not have a control group.

Settings and conduct

Exercises will be done for 4 weeks (3 sessions/week). During each session after 10 minutes warming up,endurance training includes treadmills, bicycle and arm ergonomic for 15-20 minutes with Vo2 max = 60% for Elementary sessions, and gradually 60 minutes with Vo2 max = 70-80% for final sessions. Upon completion of endurance training, resistance training include weight lifting. In this exercise, one repetition maximum of the person is calculated first and 50-60% of the 1RM for a set with 15-10 repeats. Gradually, the sets number will reach 3. Static stretching of the entire body and finally cool down for 10 minutes.

Participants/Inclusion and exclusion criteria

Mild to moderate asthma ؛ Absence of acute illnesses that are in contradiction with exercise ؛ Age limit 20 to 60 years Severe asthma and acute diseases that is exacerbated by exercise ؛ Cardiovascular and chronic inflammatory diseases ؛ Acute infections ؛Malignant diseases and immune deficiency

Intervention groups

After diagnosis of asthma of participants, patients in one group are subjected to intervention with strength and endurance exercises . At the end of the project (30 days), to determine the effect of the intervention, the rate Changes in lung function and asthma attacks , clinical signs, changes in asthma attacks, total and types of WBCs and inflammatory factors will be measured

Main outcome variables

Evaluation of disease symptoms and lung function tests Measurement of Eosinophil peroxidase, C-reactive protein, eNO Total and types of WBCs Measurement cytokines and inflammatory mediators (TNFα, IL-6 , IL-8, IgE ، IgG) in serum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180418039348N2**
Registration date: **2018-07-14, 1397/04/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-14, 1397/04/23**
Update count: **0**

Registration date

2018-07-14, 1397/04/23

Registrant information

Name

Javad Boskabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-11, 1397/04/20

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of rehabilitation (strength and endurance exercises) on respiratory symptoms, lung function indexes and some inflammatory mediators in asthmatic patients.

Public title
The effect of rehabilitation on respiratory symptoms and lung function indexes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Mild to moderate bronchial asthma disease based on spirometric testing and having clinical symptoms of respiratory tract Absence of acute illnesses that are in contradiction with exercise Age limit 20 to 60 years Giving written consent Having a commitment to doing research steps
Exclusion criteria:
Severe asthma that is exacerbated by exercise Acute diseases that are exacerbated by exercise Cardiovascular disease Chronic inflammatory diseases Acute infections Malignant diseases Having autoimmune diseases and immune deficiency
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
کمیته اخلاق دانشگاه علوم پزشکی مشهد
Street address
مشهد، بلوارشهید فکوری، حدفاصل میدان شهیدجوان وآل شهیدی، شهرك دانش وسلامت
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Approval date
2017-03-04, 1395/12/14
Ethics committee reference number
IR.MUMS.fm.REC.1395.530

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
Asthma
ICD-10 code description
J45

Primary outcomes

1

Description
Improvement in respiratory status and spirometry tests
Timepoint
At the beginning of the study and 30 days after the start of the study
Method of measurement
Measurement with using a spirometer device and pulmonary function tests

2

Description
Measuring cytokines and inflammatory mediators (such as IgE ، IgG TNFα, IL-6 and IL-8) in serum
Timepoint
At the beginning of the study and 30 days after the start of the study
Method of measurement
Use of special kits and protocols

3

Description
Total number and types of white blood cells in the blood
Timepoint
At the beginning of the study and 30 days after the start of the study
Method of measurement
Using a special laboratory device for counting white

blood cells

Secondary outcomes

1

Description
Measurement concentration of fractional exhaled nitric oxide (FeNO)
Timepoint
At the beginning of the study and 30 days after the start of the study
Method of measurement
Use of special kits and protocols

2

Description
Measurement of C-reactive protein (CRP)
Timepoint
At the beginning of the study and 30 days after the start of the study
Method of measurement
Use of special kits and protocols

Intervention groups

1

Description
Intervention group: Exercise exercises will be done for 4 weeks (3 sessions per week). During each session after warming up, for 10 minutes, endurance training includes treadmills, bicycle and arm ergonomic for 15-20 minutes with Vo2 max = 60% for Elementary sessions, and gradually 60 minutes with Vo2 max = 70-80% for final sessions. Upon completion of endurance training, resistance training include weight lifting. In this exercise, one repetition maximum of the person is calculated first and 50-60% of the 1RM for a set with 15-10 repeats. Gradually, the number of sets will reach 3. Static stretching of the entire body and finally cool down for 10 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Heart and lung rehabilitation department of Imam Reza Hospital, Mashhad
Full name of responsible person
Mohammad Sadegh Haghi
Street address
Khorasan Razavi - Mashhad - Imam Reza Hospital Square (AS) - Imam Reza Hospital
City
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emamreza@mums.ac.ir
Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi (Research Deputy of Mashhad University of Medical Sciences)
Street address
Ghoreishi building, Daneshgah Street Mashhad Khorasan Razavi Iran, Islamic Republic of Iran
City
Mashhad
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91375-345
Phone
+98 51 3882 3255
Email
Tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Javad Boskabadi
Position
Lack scientific grade-Pharmacist
Latest degree

Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Departement of Physiology - Mashhad University of Medical Sciences - Azadi Square - Mashhad - Iran

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Person responsible for scientific inquiries

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Professor

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Physiology

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Person responsible for updating data

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Position
Lack scientific grade-Pharmacist

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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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
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
Data information will be published in article form.

When the data will become available and for how long
Starting data access is six months after the article is printed.

To whom data/document is available
Researchers in the field of medical science will be able to access the data.

Under which criteria data/document could be used
Investigating requests will be reviewed by the research team.

From where data/document is obtainable
Applicants must only coordinate with the responsible designer (Dr. Mohammad Hossein Boskabady) with access to the data only with the help of e-mail. Email address: boskabadymh@mums.ac.ir

What processes are involved for a request to access data/document
After sending the request to the email of the responsible designer and the review of the type of request will eventually be notified within twenty days.

Comments