Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of Pulmonary rehabilitation effects on skeletal muscle condition, pulmonary function and quality of life in victims of chemical warfare

Protocol summary

Study aim
We hypothesise that, as is the case in COPD patients, pulmonary rehabilitation will improve the health of this patient group.

Design
We outline the protocol for an assessor blind, two-armed, parallel-design randomized controlled clinical trial

Settings and conduct
The pulmonary rehabilitation, trial activities and other clinical services will be delivered in Tehran's Khatam-ol-Anbia Hospital. This hospital is a sub-specialized centre equipped with specialized personnel and advanced equipment including a cardio-pulmonary rehabilitation hall.

Participants/Inclusion and exclusion criteria
The participants are chemical warfare victims who have been exposed to mustard gas, residing in Tehran and its suburbs with symptomatic lung disease. Inclusion criteria include, FEV1 < 80%, MRC dyspnoea score ≥ 3 . Exclusion criteria; 1) any type of debilitating clinical condition that prevents the patient from participating in the rehabilitation program –such as, arthritis, 2) any type of clinical condition that will endanger the patient during the physical exercises –such as, uncontrolled cardiac diseases, 3) the presence of other non-chemical related pulmonary diseases like asthma, 4) active malignancy 5) severe cognitive disorder and psychiatric disease that is associated with memory disorder.

Intervention groups
In addition to the usual treatment, the intervention group will receive pulmonary rehabilitation services. The pulmonary rehabilitation intervention will include a combination of physical exercises, educational programs and psychosocial support. The physical exercises will include endurance and strength components tailored to each individual's conditions. Both the upper and lower limbs will be exercised, though with greater emphasis on the legs

Main outcome variables
Primary endpoint will be change in cycle endurance time at 70% baseline exercise capacity at six weeks

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2016051127848N1**
Registration date: **2016-05-24, 1395/03/04**
Registration timing: **prospective**

Last update: **2018-02-07, 1396/11/18**
Update count: **1**

Registration date
2016-05-24, 1395/03/04

Registrant information

Name
Mohamad Reza Sedighi Moghadam

Name of organization / entity
Chemical Warfare Victims Affairs Center

Country
Iran (Islamic Republic of)

Phone
+98 21 8830 7246

Email address
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Recruitment status
Recruitment complete

Funding source
Foundation of Martyrs and Veterans Affairs

Expected recruitment start date
2016-06-04, 1395/03/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Pulmonary rehabilitation effects on skeletal muscle condition, pulmonary function and quality of life in victims of chemical warfare

Public title

Pulmonary rehabilitation in chemical victims

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patients with history of sulfur mustard exposure FEV1 lower than 80% predicted MRC dyspnoea score ≥ 3

Exclusion criteria:

any type of debilitating clinical condition that prevents the patient from participating in the rehabilitation program –such as, arthritis any type of clinical condition that will endanger the patient during the physical exercises –such as, uncontrolled cardiac diseases the presence of other non-chemical related pulmonary diseases like asthma active malignancy severe cognitive disorder and psychiatric disease that is associated with memory disorder

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the participants according to the inclusion and exclusion criteria, baseline assessments will be performed .The participants will be randomized into two control and intervention groups. The random sequence will be determined from the randomization website (http://www.jerrydallal.com/random/permute.htm) in blocks of four

Blinding (investigator's opinion)

Single blinded

Blinding description

The technicians who are responsible for randomization , the assessors and the safety committee and data monitoring are blind to the study.The two groups are identified by letters A and B. In order to protect confidentiality in all stages of the trial, each participant will be assigned a unique identification code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Organizational Committee of Ethics in Biomedical Research Foundation of Martyrs and Veterans Affairs

Street address

No 17,Farokh Street,Moghadas Ardebili Street

City

Tehran

Province

Tehran

Postal code

1985946563

Approval date

2016-04-20, 1395/02/01

Ethics committee reference number

87-E-R-102

Health conditions studied

1

Description of health condition studied

chronic respiratory disorders due to sulfur mustard inhalation

ICD-10 code

J68.4

ICD-10 code description

Chronic respiratory conditions due to chemicals, gases, fumes and vapors

Primary outcomes

1

Description

Endurance Time

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using an electronically braked cycle ergometer at 70% of Wmax to volitional exhaustion

Secondary outcomes

1

Description

Lung flows and volumes

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using body plethysmography

2

Description

single-breath diffusing capacity

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using DLCO

3

Description

Vo2max

Timepoint

before intervention

Method of measurement

by using ergospirometry

4

Description

Quadriceps muscle strength

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using Biodex: Participants will perform 30 sequential volitional maximal contractions at an angular velocity of 90°/s, while seated upright and with the hip joint in 90° of flexion. Quadriceps muscle strength was defined as the highest peak torque (Newton-meter (Nm)).

5

Description

AT

Timepoint

before intervention

Method of measurement

by using ergospirometry

6

Description

O2 pulse

Timepoint

before intervention

Method of measurement

by using ergospirometry

7

Description

Quadriceps muscle endurance

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using Biodex: Participants will perform 30 sequential volitional maximal contractions at an angular velocity of 90°/s, while seated upright and with the hip joint in 90° of flexion. Quadriceps muscle endurance was defined as the total amount of delivered work (Joules (J)) during the set of 30 repetitions

8

Description

Cross-sectional area of the rectus femoris (RFCSA)

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by Cross-sectional area of the rectus femoris (RFCSA) will be measured by B-mode ultrasonography using an 8 MHz 5.6 cm linear transducer, similar to the method of de Bruin et al

9

Description

FFM

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using single-frequency BIA (Bioelectrical Impedance Analyser)

10

Description

BMI

Timepoint

before intervention , 6th week, 12th month

Method of measurement

weight(kg)/height^2(m^2)

11

Description

Total distance walked during 6 minutes

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using 6MWT

12

Description

Anxiety and Depression

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using HADS

13

Description

quality of life

Timepoint

before intervention , 6th week, 12th month

Method of measurement

by using SGRQ

14

Description
Number of exacerbations (defined as episodes of increased respiratory symptoms requiring a change in medication)
Timepoint
monthly
Method of measurement
by asking the patient

15

Description
Number of hospitalization due to respiratory diseases
Timepoint
monthly
Method of measurement
by asking the patient and reviewing medical records

16

Description
GH
Timepoint
before intervention
Method of measurement
Lab Test

17

Description
IGF-1
Timepoint
before intervention
Method of measurement
Lab Test

18

Description
high sensitivity CRP
Timepoint
before intervention
Method of measurement
Lab Test

19

Description
Testosterone
Timepoint
before intervention
Method of measurement
Lab Test

20

Description
distance of daily walking
Timepoint
a week before intervention, 7th week and 12th month
Method of measurement
by using pedometer

21

Description
healthcare utilisation
Timepoint
at the end of study
Method of measurement
according to medical records

22

Description
dyspnea
Timepoint
before intervention , 6th week, 12th month
Method of measurement
by using Borg Scale

23

Description
fatigue
Timepoint
before intervention , 6th week, 12th month
Method of measurement
by using Borg Scale

Intervention groups

1

Description
Intervention: Pulmonary rehabilitation will be a mix of aerobic endurance training and strength training as well as education in self management. Patients will attend 3 times per week for 6 weeks.
Category
Rehabilitation

2

Description
Control: usual treatment without any additional intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Ol Anbia Hospital
Full name of responsible person
Iraj Arabi MD.
Street address
Khatam Ol Anbia Hospital, Rashid Yasemi Street, Above Mirdamad Blvd, Vali-Ye-Asr St.
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Postal code
9815733345
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Email
info@khatamhospital.org
Web page address
http://www.khatamhospital.org/index.php

2

Recruitment center
Name of recruitment center
Sasan Hospital
Full name of responsible person
Ali Tavakoli Mehrgerdi MD.
Street address
No 43, Keshavarz Ave.
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Tehran
Province
Tehran
Postal code
14154
Phone
+98 21 8896 5170
Email
info@sasanhospital.com
Web page address
http://www.sasanhospital.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Health Department of Foundation of Martyrs and Veterans Affairs
Full name of responsible person
Abd ol Reza Abbaspour MD.
Street address
Talebial Alley, Taleghani Street
City
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Postal code
1234567890
Phone
+98 21 8831 3219
Email
info@isaar.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Health Department of Foundation of Martyrs and Veterans Affairs
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Janbazan Medical Engineering Research Center
Full name of responsible person
Mohamad Reza Sedighi Moghadam MD. MPH
Position
researcher/general practitioner /MD. MPH
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Pasteur Institute of Iran
Full name of responsible person
Mostafa Ghanei MD.
Position
Head of Institute, pulmonologist
Latest degree
Subspecialist
Other areas of specialty/work
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12th Frvardin Street, Enghelab Square
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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Janbazan Medical Engineering Research Center

Full name of responsible person

Mohamad Reza Sedighi Moghadam MD. MPH

Position

researcher/general practitioner /MD. MPH

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Web page address

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

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people.

When the data will become available and for how long

The start of the access period is one year after the publication of the results.

To whom data/document is available

Data will only be available to researchers in universities and scientific centers .

Under which criteria data/document could be used

Applicants must announce their goals and plans on how to use the data to be decided on by case basis.

From where data/document is obtainable

Janbazan Medical and Engineering Research Center (JMERC), NO.17, Farrokh St., Moghaddas Ardebily Ave., Chamran Highway, Tehran, Iran Tehran Iran Phone: +98 2122415367 Fax: +98 2122418180 http://www.jmerc.ac.ir

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

The request is submitted to the supervisor through JMERC. In case of initial agreement, the Reaserch Committee will make the final decision.

Comments