Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the Impact of 7% Sodium Chloride Nebulization on Lung Function and Quality of Life in Chemical War Veterans

Protocol summary

Study aim

Effect of 7% Sodium Chloride Administered via Mesh Nebulizer on Pulmonary Function and Quality of Life in Chemical Warfare Veterans

Design

A double-blind, parallel-group, stratified block-randomized, phase 2-3 controlled clinical trial on 62 chemical warfare veterans

Settings and conduct

The study will be conducted as a double-blind, randomized clinical trial in the specialized pulmonary clinic of Baqiyatallah Hospital in Tehran. After initial screening and eligibility verification by a pulmonary specialist, participants will be randomly assigned to two intervention and control groups. Clinical assessments and pulmonary function tests will be performed at weeks 0, 4, and 8, and data will be collected and analyzed by an independent team without knowledge of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 40 and 70 years, medical confirmation of lung complications due to mustard gas, absence of acute respiratory infection in the past 4 weeks, and no changes in baseline medications in the past month. Exclusion criteria: unrelated respiratory diseases, heart or Renal failure, and smoking/alcohol consumption in the past 6 months.

Intervention groups

the intervention group, which will receive a 7% NaCl solution twice daily for 8 weeks, and the control group, which will receive a 0.9% normal saline solution according to the same protocol. Both solutions are manufactured by Saha Daru Company.

Main outcome variables

Forced expiratory volume in the first second, forced vital capacity, peak expiratory flow, total score of the Respiratory Disease Quality of Life Questionnaire, frequency of cough episodes, volume of sputum production, dyspnea, and C-reactive protein level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250524065876N1**
Registration date: **2025-08-23, 1404/06/01**
Registration timing: **prospective**

Last update: **2025-08-23, 1404/06/01**
Update count: **0**

Registration date

2025-08-23, 1404/06/01

Registrant information

Name

mansoureh molaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-02, 1404/06/11

Expected recruitment end date

2025-11-02, 1404/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Impact of 7% Sodium Chloride Nebulization on Lung Function and Quality of Life in Chemical War Veterans

Public title

Effect of 7% Hypertonic Saline Nebulization on Lung Function and Quality of Life in Chemical Warfare Veterans

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chemical warfare veteran with documented exposure to sulfur mustard gas Medically confirmed pulmonary complications due to sulfur mustard exposure Moderate to severe degree of pulmonary involvement Age between 40-70 years No acute respiratory infection in the past 4 weeks No changes in baseline medications in the past month Willingness to participate and sign informed consent

Exclusion criteria:

Severe asthma or bronchiectasis unrelated to chemical injury Class III or IV heart failure according to New York Heart Association criteria Renal failure Advanced liver disease Uncontrolled hypertension History of allergic reaction to hypertonic sodium chloride (7%) Tobacco/waterpipe use within the past 6 months Regular alcohol consumption Severe cognitive impairment Current ICU admission or requirement for mechanical ventilation Unwillingness to participate or sign informed consent

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization with a block size of 4 will be used to allocate participants into two groups: the intervention group (receiving 7% NaCl via mesh nebulizer) and the control group (receiving normal saline). Randomization will be performed at the individual level, with stratification based on the severity of pulmonary disease (moderate/severe). The random sequence will be generated using R software and placed in sealed envelopes to ensure proper allocation concealment. An independent colleague will be responsible for managing the envelopes, and both patients and researchers will remain blinded to group assignments until the intervention begins (double-blind). This method prevents imbalance between groups and has been designed in accordance with CONSORT standards for randomized clinical trials.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a strict double-blinding system is designed in which both patients and investigators will be unaware of the type of treatment they will receive. Patients will be treated without knowing the actual content of the nebulized solutions (7% NaCl or normal saline), while the treating physicians, nurses, outcome assessors, and data collection team will also be unaware of the group allocation of patients. Drug solutions will be prepared and delivered by the project pharmacist in completely identical containers without special markings. Statistical analysts will also not be aware of the grouping codes until the end of the primary analysis phase. Only the safety and data monitoring committee will have access to the actual data to monitor the safety of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Baqiyatallah Hospital

Street address

No. 7, South Sheikh Bahaei St., Molla Sadra St., Tehran

City

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Province

Tehran

Postal code

1435916471

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.BMSU.BAQ.REC.1403.237

Health conditions studied

1

Description of health condition studied

Chemical pneumonitis induced by sulfur mustard gas

ICD-10 code

J68.0

ICD-10 code description

Bronchitis and pneumonitis due to chemicals, gases, fumes and vapors

Primary outcomes

1

Description
Forced Expiratory Volume in 1 second (FEV1)
Timepoint
Weeks 0, 4, and 8 post-intervention
Method of measurement
Standard spirometry using calibrated equipment

2

Description
Respiratory Quality of Life Questionnaire Total Score
Timepoint
Weeks 0 and 8 post-intervention
Method of measurement
St. George Respiratory Quality of Life Questionnaire

3

Description
serum C-reactive protein (CRP) level
Timepoint
Weeks 0 and 8 post-intervention
Method of measurement
ELISA using standardized kits

Secondary outcomes

1

Description
Forced Vital Capacity (FVC)
Timepoint
Weeks 0, 4, and 8 after intervention
Method of measurement
Standard spirometry using calibrated equipment

2

Description
Peak Expiratory Flow (PEF)
Timepoint
Weeks 0, 4, and 8 after intervention
Method of measurement
Spirometry

3

Description
Frequency of coughing episodes
Timepoint
Weeks 0, 4, and 8 after intervention
Method of measurement
Patient-reported daily diary (visual analog scale)

4

Description
Sputum production volume
Timepoint
Days 1 and 3, weeks 0, 4, and 8 after intervention
Method of measurement
Graded container measurement (morning collection)

5

Description
Dyspnea
Timepoint
Weeks 0 and 8 after intervention
Method of measurement
Revised Medical Research Council Scale

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive 7% sodium chloride solution (hypertonic saline) through an Omron NE-U22 mesh nebulizer device. The treatment protocol includes administering 4 ml of the solution twice a day (every 12 hours) for 8 weeks. Each nebulization session lasts about 10-15 minutes and patients are required to observe a 30-minute interval before and after meals and rinse their mouth after each use. The sterile solution used is provided by saha Pharmaceutical Company and all patients receive complete practical training on the correct use of the device before starting the intervention.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive 0.9% normal saline solution (placebo) with the same Omron NE-U22 mesh nebulizer device, with a completely similar protocol to the intervention group (4 ml, twice a day for 8 weeks). The placebo solution is prepared by the same manufacturer (saha) and is presented in containers that are completely similar in shape and packaging. All instructions for use, patient education, weekly follow-ups, and drug prohibitions in this group are also followed exactly the same as in the intervention group so that the specific effects of hypertonic saline can be properly assessed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Ali Qazvini
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Seyed Javad Hoseini
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Mollasadra Street, Sheikh Bahaei South Street, Vanak Square, Tehran, Iran
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
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Position
Resident
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available