

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

+98 21 8804 0060

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mollaeimansoure5@gmail.com

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 Tehran 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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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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Mansoureh Molaei
Position

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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