# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)

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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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Mollasadra Street, Sheikh Bahaei South Street, Vanak

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Bagheiat-allah University of Medical Sciences
**Full name of responsible person**
Seyed Javad Hoseini
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**Email**
research@bmsu.ac.ir
**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
**Full name of responsible person**
Mansoureh Molaei
**Position**
Resident
**Latest degree**
Specialist
**Other areas of specialty/work**
Internal Medicine
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## Person responsible for updating data

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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