Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of antioxidant effects of NAC and vitamin B6 in comparison with NAC and placebo, in chemical warfare victims Chronic pulmonary lesions

Protocol summary

Study aim
Evaluation of antioxidant effects of NAC and vitamin B6 in comparison with NAC alone, in chemical warfare victims Chronic pulmonary lesions

Design
This study is a randomized, double-blinded, placebo-controlled, parallel, clinical trial, in which 56 War chemical gas victims with chronic lung lesions, who will consciously and freely satisfy to participate in the study, will be entered the trial and accidentally will be assigned to intervention or control group, then be monitored for 6 weeks.

Settings and conduct
Patients will randomly assigned to intervention or control group and, according to their group's protocol, will take the medication for 6 weeks. Prior to the intervention, patients' demographic information and chemical ware gas history, quality of life, and levels of oxidative stress biomarkers will recorded. Six weeks later, at the end of the study, the following will be reviewed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Chronic lung lesions caused by war chemical gases have been proven; According to the patient's spirometry results, the pulmonary injury is not severe; The patient should have freely informed written consent to participate in the study. Exclusion criteria: Suffering from lung function-related diseases of lung origin, including asthma, bronchiectasis, etc. Suffering from lung function-related diseases of non-lung origin, including ALS, kyphosis, etc.

Intervention groups
In intervention group, patients will receive 600 mg of NAC effervescent tablets, 3 times a day, and Tablet vitamin B6 50 mg once daily for 6 weeks. In control group, patients will receive 600 mg of NAC effervescent tablets, 3 times a day, and Tablet vitamin B6 placebo once daily for 6 weeks.

Main outcome variables
Spirometry parameters changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001165N54**
Registration date: **2020-05-23, 1399/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-23, 1399/03/03**
Update count: **0**

Registration date
2020-05-23, 1399/03/03

Registrant information

Name
Yunes Panahi

Name of organization / entity
Baqiyatallah University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8821 1524

Email address
yunespanahi@bmsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-11, 1398/08/20

Expected recruitment end date
2020-11-10, 1399/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of antioxidant effects of NAC and vitamin B6 in comparison with NAC and placebo, in chemical warfare victims Chronic pulmonary lesions

Public title
Evaluation of antioxidant effects of NAC and vitamin B6 in comparison with NAC and placebo, in chemical warfare victims Chronic pulmonary lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Chronic lung lesions caused by war chemical gases have been proven; According to the patient's spirometry results, the pulmonary injury is not severe; The patient should have freely informed written consent to participate in the study.
Exclusion criteria:
Suffering from lung function-related diseases of lung origin, including asthma, bronchiectasis, etc. Suffering from lung function-related diseases of non-lung origin, including ALS, kyphosis, etc.
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method is used to randomized the patients. For randomization, we visited the www.sealedenvelope.com, then randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (which was selected due to the small sample size, 4)were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two intervention groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both patients and physicians participating in this clinical trial are blinded about the prescribed type of drug (main drug / placebo).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah Medical Sciences University
Street address
Mullasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۷۱
Approval date
2017-11-03, 1396/08/12
Ethics committee reference number
IR.BMSU.REC.1396.721

Health conditions studied

1

Description of health condition studied
war chemical gas pulmonary disease
ICD-10 code
J68.4
ICD-10 code description
Chronic respiratory conditions due to chemicals, gases, fumes and vapors

Primary outcomes

1

Description
Spirometry parameters changes
Timepoint
Before intervention, then 6 weeks later
Method of measurement
Spirometer

Secondary outcomes

1

Description
Quality of life
Timepoint
Before intervention, then 6 weeks later

Method of measurement
ACT Questionnaire

2

Description
Total antioxidant capacity
Timepoint
Before intervention, then 6 weeks later
Method of measurement
Total Antioxidant Capacity Assay Kit

3

Description
Malondialdehyde (MDA)
Timepoint
before intervention, then 6 weeks later
Method of measurement
human Elisa kit

4

Description
Superoxide dismutase (SOD)
Timepoint
before intervention, then 6 weeks later
Method of measurement
human Elisa kit

Intervention groups

1

Description
Intervention group: NAC effervescent tablets 600 mg, 3 times a day,and 50 mg of vitamin B6 tablets, PO, daily, for 6 weeks.
Category
Treatment - Drugs

2

Description
Control group: NAC effervescent tablets 600 mg, 3 times a day,and Vitamin B6 Placebo tablets, PO, daily, for 6 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Mostafa Ghanei
Street address
Mollasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۷۱
Phone
+98 21 8248 2503
Email
mghaneister@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Baqiyatallah University of Medical Sciences
Full name of responsible person
Gholamhosein Alishiri
Street address
Mollasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۷۱
Phone
+98 21 8248 2503
Email
R.bmsu@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Baqiyatallah 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
Mohammadjavad Ershadi
Position
Assistant
Latest degree

Subspecialist

Other areas of specialty/work
Pulmonary disease

Street address
Mollasadra St., Vanak Sq.

City
Tehran

Province
Tehran

Postal code
۱۴۳۵۹۱۵۳۷۱

Phone
+98 21 8248 2503

Email
mjershad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Yunes Panahi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Critical Care Pharmacotherapy

Street address
Mollasadra St., Vanak Sq.

City
Tehran

Province
Tehran

Postal code
1435916471

Phone
+98 21 8248 2503

Email
Yunespanahi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Parisa Kianpour

Position
Assistant

Latest degree
Specialist

Other areas of specialty/work
Pharmacotherapy

Street address
Pharmacy faculty, Tehran University of Medical Science, 16-Azar Ave., Enghelab Sq.

City
Tehran

Province
Tehran

Postal code
1991953381

Phone
+98 21 6695 4709

Email
Parisa_kianpour@yahoo.com

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
Undecided - It is not yet known if there will be 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