Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of efficacy and safety of Iranian version of NAC and comparing it with foreign sample of NAC in controlling pulmonary symptoms caused by sulfur mustard in chemically-wounded patients and veterans

Protocol summary

Summary

Objective of trial: Demonstrate efficacy and safety of Iranian version of NAC and comparing it with foreign sample of NAC in controlling pulmonary symptoms caused by sulfur mustard in chemically-wounded patients and veterans and introducing an effective therapeutic alternative for patients suffering from chronic pulmonary injuries caused by sulfur mustard and introducing the better and cheaper substitute anti-oxidant Oslyt instead of Fluimucil in order to decrease clinical and financial problems of patients Study design: Parallel-Group Non-Inferiority Double-Blind Randomized Clinical Trial Both Patients and those measuring the outcomes of the study (researchers) were blinded during the trial,i.e., double-blind and the data analysis committee (analysts) was not blinded during the trial Inclusion Criteria: documented exposure to sulfur mustard; documented diagnosis of chronic pulmonary disease due to mustard gas (histological evidence from previous biopsies) Exclusion Criteria: any severe side effects of N-acetylcysteine (anaphylactoid reactions); consuming less than 80% of the prescribed NAC Sample size: 84 individuals One group will consume a total daily dosage of 1800 mg (3 times a day and each time one effervescent 600 mg tablet) of NAC from the Iranian Osvah pharmaceutical company (Oslyt®, Osvah Pharmaceutical Company, Tehran, Iran) and the other group will consume a total daily dosage of 1800 mg (3 times a day and each time one effervescent 600 mg tablet) of NAC from the foreign Zambon pharmaceutical company (Fluimucil®, Zambon Switzerland Ltd., Cadempino, Switzerland). The duration of the trial will be 4 months and patients will receive a daily dosage of 1800 mg of either oslyt or fluimucil for 4 months. Primary outcome or outcomes of trial: the difference and changes of severity of dyspnea, wake-up dyspnea, cough and presence or no-existence of sputum and difference and changes of spirometric indices after consuming NAC

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506181165N5**
Registration date: **2015-07-13, 1394/04/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-13, 1394/04/22

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Baqiyatallah University of Medical Sciences Osvah Pharmaceutical Company

Expected recruitment start date

2015-07-06, 1394/04/15

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of efficacy and safety of Iranian version of NAC and comparing it with foreign sample of NAC in controlling pulmonary symptoms caused by sulfur mustard in chemically-wounded patients and veterans

Public title

Examining the effect of NAC tablet on improving lung problems caused by mustard gas in chemically-wounded patients and veterans

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: documented exposure to sulfur mustard; documented diagnosis of chronic pulmonary disease due to mustard gas (histological evidence from previous biopsies); no history of tuberculosis; no history of resection of one or more lobes of lung Exclusion criteria: pneumonia; acute bronchitis; smoking cigarettes; being a substance abuser; any illness in which the medications could not be stopped; occurrence of any severe side effects of N-acetylcysteine (anaphylactoid reaction); use of any kind of antioxidant drugs; deterioration of clinical conditions during the course of the study; consuming less than 80% of allocated NAC medication

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

We used the block randomization technique as the randomization procedure in our trial; if Oslyt group is shown by the letter A and Fluimucil group by B, randomization blocks are quaternary, i.e., AABB, BBAA, BABA, ABBA, ABAB and BAAB. In total, 21 blocks are established and patients are allocated to Oslyt or Fluimucil by these blocks and therefore, randomized.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Sheykh Bahaei-South st., Mollasadra st., Vanak square, Tehran

City

Tehran

Postal code

Approval date

2015-06-17, 1394/03/27

Ethics committee reference number

BMSU.REC.1394.107

Health conditions studied

1

Description of health condition studied

Chronic respiratory disorders caused by chemical weapons (sulfur mustard; mustard gas)

ICD-10 code

J68.4, Y36

ICD-10 code description

due to inhalation of chemicals, gases, fumes and vapours

Primary outcomes

1

Description

Cough

Timepoint

Before intervention, four months after intervention (end of intervention)

Method of measurement

likert scale from 1 to 5: 1=I did not have cough 2=I have cough, but it is not a serious problem 3=I have cough, sometimes disturbs my work 4=I have disturbing cough, usually disturbs my work 5=I have disturbing cough, always disturbs my work

2

Description

Dyspnea

Timepoint

Before intervention, four months after intervention (end of intervention)

Method of measurement

likert scale from 1 to 5: 1=There is no dyspnea 2=Dyspnea only in extraordinary exercises 3=Dyspnea

in ordinary exercise 4=Dyspnea in mild exercise 5=Dyspnea in rest

Secondary outcomes

1

Description
Wake-up dyspnea
Timepoint
Before intervention, four months after intervention (end of intervention)
Method of measurement
likert scale from 1 to 4: 1=I never woke up due to dyspnea 2=I wake up less than once a week 3=I wake up once a week 4=I wake up more than twice a week

2

Description
Side effects of Iranian NAC (Oslyt) and Foreign NAC (Fluimucil)
Timepoint
At the end of the second week of the trial
Method of measurement
At the end of the second week of the trial and in a clinical visit, patients in both groups were asked about the side effects of NAC including nausea, vomiting, unpleasant taste of tablet, gastrointestinal distress, diarrhea, constipation and symptoms related to anaphylactoid reactions like urticaria, rash, suffocation feeling, dysphagia, dizziness, reduced blood pressure, pruritus and etc.

3

Description
Sputum
Timepoint
Before intervention, four months after intervention (end of intervention)
Method of measurement
Sputum was reported as 0 for absence and 1 for presence

4

Description
Delta Cough
Timepoint
Four months after intervention (end of intervention)
Method of measurement
Cough Score at month 4 minus cough score at month 0

5

Description
Delta dyspnea
Timepoint
Four months after intervention (end of intervention)
Method of measurement
Dyspnea Score at month 4 minus dyspnea score at month 0

6

Description
Delta Wake-up dyspnea
Timepoint
Four months after intervention (end of intervention)
Method of measurement
Wake-up Dyspnea Score at month 4 minus wake-up dyspnea score at month 0

7

Description
FEV1
Timepoint
Before intervention, two months after intervention, four months after intervention (end of intervention)
Method of measurement
Measured by a HI-801 Chest M.I. Spirometer, Tokyo, Japan and unit of measurement is liter

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Description
FVC
Timepoint
Before intervention, two months after intervention, four months after intervention (end of intervention)
Method of measurement
Measured by a HI-801 Chest M.I. Spirometer, Tokyo, Japan and unit of measurement is liter

9

Description
FEV1/FVC
Timepoint
Before intervention, two months after intervention, four months after intervention (end of intervention)
Method of measurement
FEV1 divided by FVC that has no specific unit

Intervention groups

1

Description
In the control group, patients consume the standard treatment of Foreign NAC (Fluimucil) with a total daily dosage of 1800 mg (three times a day and each time a 600 mg effervescent oral tablet) for four months
Category
Treatment - Drugs

2

Description
In the intervention group, patients consume the Iranian NAC (Oslyt) with a total daily dosage of 1800 mg (three times a day and each time a 600 mg effervescent oral tablet) for four months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah Hospital Sub-specialty Clinic

Full name of responsible person
Dr. Mostafa Ghanei-Physician-Pulmonologist-Full Professor

Street address
Third floor, Baqiyatallah Clinic building, Sheykh bahaei st., Mollasadra st., Vanak square, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research deputy of Baqiyatallah University of Medical Sciences

Full name of responsible person
Dr. Morteza Izadi-Research and technology deputy of Baqiyatallah University of Medical Sciences

Street address
Baqiyatallah University of Medical Sciences, Sheykh bahaei st., Mollasadra st., Vanak square, Tehran

City
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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
Research deputy of Baqiyatallah University of Medical Sciences

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

2

Sponsor

Name of organization / entity
Osvah Pharmaceutical Company

Full name of responsible person
Dr. Ehsan Sanati-Director of Market Research & Clinical Trials

Street address
17 Shahrivar St., Shad Abad, Karaj Old Road, Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Osvah Pharmaceutical Company

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Baqiyatallah University of Medical Sciences-Chemical Injuries Research Center

Full name of responsible person
Dr. Yunes Panahi

Position
Head of Chemical Injuries Research Center-PhD in Pharmacotherapy-Associate Professor

Other areas of specialty/work

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Web page address

http://ghanei.ir

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty