

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 Flui mucil 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)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

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

Tehran

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**Street address**

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences, Sheykhbahaei st., Mollasadra st., Vanak square, Tehran

City

Tehran

Postal code**Phone**

+98 21 8248 2507

Fax

+98 21 8821 1524

Email

yunespanahi@yahoo.com
circevaluations@yahoo.com

Web page address

http://y_panahi.cv.research.ac.ir/Default.aspx

Person responsible for scientific inquiries

Contact

Name of organization / entity

Chemical Injuries Research Center, Baqiyatallah University of Medical sciences, Qazvin University of

Full name of responsible person

Dr. Aboutaleb Simiari

Position

Resident of Internal medicine

Other areas of specialty/work**Street address**

Chemical Injuries Research Center, Baqiyatallah
University of Medical Sciences, Sheykhbahaei st.,
Mollasadra st., Vanak square, Tehran

City

Tehran

Postal code

Phone

+98 21 8248 2507

Fax

+98 21 8821 1524

Email

mghanei@hbi.irm.ghanei@bmsu.ac.ir

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