

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of melatonin administration on sleep quality in sulfur mustard exposed patients with sleep disorders

Protocol summary

Summary

The aim of current study was to evaluate the therapeutic effects of melatonin on sleep quality in SM-exposed patients with sleep disorders. This randomized, double-blind, placebo controlled clinical trial was conducted in chemical injury research center of Baqiyatallah University of Medical Sciences. According to the inclusion and exclusion criteria, as well as basic clinical findings and spirometric data, 30 SM-injured patients with mild ($FEV1 \geq 80\%$) and moderate ($50\% \leq FEV1 \leq 80\%$) lung injuries which their sleep disorders were confirmed using polysomnography at sleep clinic of Baqiyatallah hospital were included in the current survey. Patients who had a history of cigarette smoking or exposure to any other respiratory pollutants, rhinitis allergique or other allergic diseases before exposure to sulfur mustard, history of asthma, lung cancer and pulmonary tuberculosis, acute infection at upper and lower respiratory system, history of drugs consumption that are associated with pulmonary complications, and history of systemic diseases or other chronic abnormalities which are associated with lung problems (such as heart disorders, kidney diseases, hepatitis, cirrhosis), were excluded from the study. Initially, quality of sleep and daytime sleepiness and the risk of obstructive sleep apnea were assessed by the Pittsburgh Sleep Quality Index (PSQI), the Epworth Sleepiness Scale (ESS) and STOP-Bang Questionnaires, respectively then patients were randomized to the melatonin or placebo group and Melatonin (Nature Made) or placebo (Tehran-chemistry Company) were supplied in identical 3- mg tablets to be taken in a single dose 1 hour before bedtime for 8 weeks. Assessment of the sleep quality, daily sleepiness and the risk of obstructive sleep apnea were repeated at the end of the treatment for comparison.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092924267N1**

Registration date: **2015-11-23, 1394/09/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-23, 1394/09/02

Registrant information

Name

Seyyedeh Soghra Mousavi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 2515

Email address

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Recruitment status

Recruitment complete

Funding source

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-04-16, 1394/01/27

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin administration on sleep quality in

sulfur mustard exposed patients with sleep disorders

Public title
Effect of melatonin on sleep in sulfur mustard exposed patients

Purpose
Treatment

Inclusion/Exclusion criteria

- Inclusion criteria: Sulfur mustard-injured patients with mild [Forced expiratory volume in 1 second (FEV1) $\geq 80\%$] and moderate ($50\% \leq \text{FEV1} \leq 80\%$) lung damages which their sleep disorders were confirmed using polysomnography at sleep clinic of Baqiyatallah University of Medical Sciences.
- Exclusion criteria: Cigarette smoking or a history of exposure to any other respiratory pollutants; History of rhinitis allergique or other allergic diseases before exposure to sulfur mustard; History of asthma, lung cancer and pulmonary tuberculosis; Acute infection at upper and lower respiratory system; History of drugs consumption that is associated with pulmonary complications; History of systemic diseases or other chronic abnormalities which are associated with lung problems (such as heart disorders, kidney diseases, hepatitis, cirrhosis)

Age
From **45 years** old to **69 years** old

Gender
Male

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Patients were divided into two groups (melatonin and placebo) by random number table. In this study, patients and researcher were not aware of the type of intervention. the person who performed sampling of patients, gave Drug or placebo to patients and after completion of the study, researcher was aware of the type of intervention.

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, Molla Sadra Ave., Vanak Sq., Tehran, Iran

City

Tehran

Postal code

1435915371

Approval date

2014-11-02, 1393/08/11

Ethics committee reference number

IR.Bmsu.REC.1393.65

Health conditions studied

1

Description of health condition studied

Sleep Disorders

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description

Sleep Quality

Timepoint

before treatment, 8 weeks after treatment

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Daytime Sleepiness

Timepoint

before treatment, 8 weeks after treatment

Method of measurement

Epworth Sleepiness Scale

3

Description

The risk of Obstructive Sleep Apnea

Timepoint

before treatment, 8 weeks after treatment

Method of measurement

STOP Bang Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Melatonin; N acetyl 5 methoxy tryptamine; 3 mg; 3 mg oral tablet; A pill every night for 8 weeks; Nature Made

Category

Treatment - Drugs

2

Description

Placebo; 3 mg; 3 mg oral tablet, A pill every night for 8 weeks; Tehran Chemistry Company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chemical Injuries Research Center

Full name of responsible person

Seyyedeh Soghra Mousavi

Street address

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences, Molla Sadra Ave., Vanak Sq.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr Hassan Bagheri

Street address

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences, Molla Sadra Ave., Vanak Sq.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences

Proportion provided by this source

100

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

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences

Full name of responsible person

Seyyedeh Soghra Mousavi

Position

Ph.D Student of Molecular Medicine

Other areas of specialty/work

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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