Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Baqiatallah 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≥80%) and moderate (50% ≤ FEV1≤ 80%) lung injuries which their sleep disorders were confirmed using polysomnography at sleep clinic of Baqiatallah 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

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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)≥80%] and moderate (50% ≤ FEV1≤ 80%) lung damages which their sleep disorders were confirmed using polysomnography at sleep clinic of Baqiatallah 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 Comittee 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
Tehran

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
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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
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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