Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of oxygen on anxiety, sleep quality and depression of shift work nurses after night shift

Protocol summary

Study aim
Effect of oxygen on anxiety, sleep quality and depression of shift work nurses after night shift

Design
Clinical trial, Randomized, controlled, blinded trial with 56 samples in four parallel groups

Settings and conduct
After night shift, the nurses who are randomized in four groups will receive oxygen or air by care provider. The researcher, the nurse and the evaluator are blind about intervention type. The sleep quality, anxiety and depression are assessed before receiving oxygen in the first day (before receiving oxygen), and in the tenth and the twentieth days and the thirtieth day (after receiving the oxygen).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Shift work nurses in Shahid Sadoughi, Shahid Rahnemun and Afshar hospitals of Yazd who work between 8 PM till 8 AM. Exclusion criteria: Consecutive night shift, history of health problems affecting pulmonary system, psychiatric disorders, addiction, smoking, pregnancy

Intervention groups
The samples are divided into four fourteen-person groups randomly.The first group will receive oxygen with mask for 3 minutes; the second group will receive oxygen with nasal canola for 3 minutes; the third group will receive compact air with mask for 20 minutes, and fourth group will receive oxygen with mask by deep breathing for 2 minutes after night shift.

Main outcome variables
sleep quality, anxiety and depression. Age, gender, marital status, education, employment status, work experience, number of shifts in a month, pulse and blood pressure before and after intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150904023890N2**
Registration date: **2019-01-10, 1397/10/20**
Registration timing: **retrospective**

Last update: **2019-01-10, 1397/10/20**
Update count: **0**

Registration date
2019-01-10, 1397/10/20

Registrant information

Name
Fatemeh Modjallal Najjar

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 35 3827 4475

Email address
fmodjallal@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-01, 1397/09/10

Expected recruitment end date
2018-12-31, 1397/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oxygen on anxiety, sleep quality and depression of shift work nurses after night shift

Public title
Effect of Oxygen on sleep, anxiety and depression
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Emergency shift nurses work between 8 PM and 8 AM in the next morning
Exclusion criteria:
History of health problems affecting pulmonary system, psychiatric disorders, addiction, smoking, pregnancy
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the patients were divided into four fourteen-person groups by simple randomization and proper assignment between three hospitals.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the participants are blind about gas type; also the researcher and the evaluator are blind about gas type; but the selected person who do the intervention is aware about the gas kind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences
Street address
Yazd University of Medical Sciences Central Building, Bahonar Square
City
Yazd
Province
Yazd
Postal code
8916886931
Approval date
2018-11-27, 1397/09/06
Ethics committee reference number
IR.SSU.MEDICINE.REC.1397.151

Health conditions studied

1

Description of health condition studied
Sleep quality in shift work nurse
ICD-10 code
G47.2
ICD-10 code description
Disorders of the sleep-wake schedule

2

Description of health condition studied
Depression
ICD-10 code
F43.2
ICD-10 code description
States of subjective distress and emotional disturbance, usually interfering with social functioning and performance, arising in the period of adaptation to a significant life change or a stressful life event.

3

Description of health condition studied
Anxiety
ICD-10 code
F41.3
ICD-10 code description
Symptoms of anxiety mixed with features of other disorders in F42-F48. Neither type of symptom is severe enough to justify a diagnosis if considered separately.

Primary outcomes

1

Description
Pittsburgh Sleep Quality Index score for sleep quality
Timepoint
Before study, Days 10, 20 and 30
Method of measurement
Pittsburgh Sleep Quality Index

2

Description
Beck's Depression Inventory score
Timepoint
Before study, Days 10, 20 and 30
Method of measurement
Beck's Depression Inventory

3

Description
Subjective anxiety feeling scale score from 1 to 10 for anxiety
Timepoint
Before study, Days 10, 20 and 30
Method of measurement
Subjective anxiety feeling scale score from 1 to 10

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: : Oxygen with mask, 3 liter per minute for 20 minute after finishing night shift in rest room
Category
Treatment - Drugs

2

Description
Intervention group: Oxygen with nasal canola, 3 liter per minute for 20 minute after finishing night shift in rest room
Category
Treatment - Drugs

3

Description
Intervention group: Compact air with mask, 3 minute for 20 minute after finishing night shift in rest room
Category
Treatment - Drugs

4

Description
Intervention group: Oxygen 3 liter per minute with mask by deep breathing for 2 minute after finishing night shift in rest room.In this study deep breathing is receiving oxygen by deep inspiration, holding that for 5 second, then expiration.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadughi Hospital
Full name of responsible person
Fatemeh Samadi
Street address
Ebne Sina Blvd, Shahid Ghandi Blvd, Safaeieh
City
Yazd
Province
Yazd
Postal code
8916886931
Phone
+98 35 3822 4000
Fax
+98 35 3822 4100
Email
Sadoghi-hospital@ssu.ac.ir
Web page address
http://ssu.ac.ir/cms/index.php?id=587

2

Recruitment center
Name of recruitment center
Shahid Dr. Rahnamoon Hospital
Full name of responsible person
Fatemeh Modjallal Najjar
Street address
Shahid Dr. Rahnamoon Hospital, Farrokhi St.
City
Yazd
Province
Yazd
Postal code
8916847477
Phone
+98 35 3626 0001
Fax
+98 35 3627 1191
Email
Rahnemoonhospital@ssu.ac.ir
Web page address
http://www.ssu.ac.ir/cms/index.php?id=590

3

Recruitment center
Name of recruitment center
Afshar Hospital
Full name of responsible person
Fatemeh Samadi
Street address
Jomhuri Eslami Blvd, Yazd Afshar Hospital
City
Yazd
Province
Yazd
Postal code
8916847477
Phone
+98 35 3525 5011
Fax
+98 35 3525 5011
Email
afsharhospital@ssu.ac.ir
Web page address
http://ssu.ac.ir/cms/index.php?id=593

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
masud mirzaei

Street address
Bahonar Square, Central Building of Yazd University of Medical Sience

City
Yazd

Province
Yazd

Postal code
8916847477

Phone
+98 35 3726 3733

Fax
+98 35 3726 3732

Email
technologydeputy@ssu.ac.ir

Web page address
http://ssu.ac.ir/cms/index.php?id=467

Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Abbas Edalatkhah

Position
Medical Doctor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
No. 7, Atlasi Alley 31, Madar Square, Safaeieh

City
Yazd

Province
Yazd

Postal code
8916859865

Phone
+98 35 3827 4475

Email
abbas_edalatkhah@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Samadi

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address
No. 7, Atlasi Alley 31, Madar Square, Safaeieh

City
Yazd

Province
Yazd

Postal code
8916859865

Phone
+98 35 3827 4475

Email
khorshidi.fs@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Modjallal Najjar

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Sq.

City
Yazd

Province
Yazd

Postal code
8916847477

Phone
+98 35 3827 4475

Fax
+98 35 3823 5055

Email
fmodjallal@ssu.ac.ir
Web page address
http://ssu.ac.ir/cms/index.php?id=467

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
Data on the main implications will be shared.
When the data will become available and for how long
6 months after article currency
To whom data/document is available
Data will only be available to academic researchers.
Under which criteria data/document could be used
Sharing the product grade based on the results of this research.
From where data/document is obtainable
Dr Abbass Edalatkhah abbas_edalatkhah@yahoo.com
What processes are involved for a request to access data/document
By request, by e-mail, mentioning the type of use and the moral obligation to not use for another purpose, data will be sent within a week.
Comments