

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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 3823 5055

##### 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**

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##### **Province**

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##### **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

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##### **Province**

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##### **Phone**

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##### **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 Science

**City**

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**Province**

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**Postal code**

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**Phone**

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**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

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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

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**Province**

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**Postal code**

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**Email**

khoshidi.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.

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**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 Edalatkah abbas\_edalatkah@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**