

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Effect of lidocaine-prilocaine cream on comfortably of CPAP mask in patients who undergone PAP-titration due to obstructive sleep apnea

#### Protocol summary

##### Study aim

Determination of patient's comfort in using mask with lidocaine-prilocaine gel compared to placebo and not using any gel

##### Design

Randomized control trial, with control group, parallel groups trial with triple blinded outcome assessment

##### Settings and conduct

The patient's discomfort with the mask being evaluated by the patient's VAS is recorded from 0 to 10 (with 4 cm water pressure and no leakage). In the first group, after washing the face with soap and water and drying the face, a thick layer of cream is applied to the nasal bridge area (1.5 g per 10 cm<sup>2</sup>) without entering the gel into eye. The applied surface is covered with a nylon. After 15 minutes the mask is re-inserted and the degree of discomfort after VAS is measured. The titration is then performed according to the AASM guideline. Tomorrow morning, the VAS will again measured regarding to difficulty in using the mask. A person's tendency to use a mask documented from 1 to 5 and the extent of refreshment on following day documented from 1 to 5. The scoring is then performed by a blind group to the study and the parameters such as the maximum pressure of CPAP has, REM percentages and sleep efficiency are measured. AHI of diagnostic polysomnography, REM percentages and sleep efficiency are also recorded along with BMI, age and sex questionnaires. The same will apply to the control group using lubricant gel and the mask without any gel.

##### Participants/Inclusion and exclusion criteria

Patients who referred to Baharlou and Imam Khomeyni hospital for CPAP titration due to obstructive sleep apnea

##### Intervention groups

Use of lidocaine-prilocaine Use of lubricant gel

##### Main outcome variables

The amount of patient is comfortably using the CPAP mask

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190602043791N1**

Registration date: **2019-11-12, 1398/08/21**

Registration timing: **prospective**

Last update: **2019-11-12, 1398/08/21**

Update count: **0**

##### Registration date

2019-11-12, 1398/08/21

##### Registrant information

##### Name

Reza Erfanian Azimzadeh Khosravi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6672 7061

##### Email address

r\_erfanian@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-21, 1398/08/30

##### Expected recruitment end date

2020-04-19, 1399/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of lidocaine-prilocaine cream on comfortably of CPAP mask in patients who undergone PAP-titration due to obstructive sleep apnea

**Public title**  
lidocaine-prilocaine cream effect on comfortably of CPAP mask

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients who refereed to Bharlou and Imam Khomeyni hospital for CPAP titration due to obstructive sleep apnea  
**Exclusion criteria:**  
 Cardiac arrhythmia, Anti arrhythmic drug class III consumption, seizure, Methemoglobinemia, allergy to anesthesia solution, absence of informed consent

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **23**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomized block randomization was performed by the StatsDirect program with seed 10, number 69 and random block size between 2 and 4 and treatment number 3. A B C code is required for each group. At night the technician (blind to AB groups) contact the code holder who is blind to each of the groups (CAB), to be informed for titration in order to use the gel in 1 or 2 or he should not use the gel. It should be explained that in Group C no gel 1 or 2 is used, it is not possible to blind technicians and patients in this group. The technician and the patient are blind to the type of material used. Gel 1 is a mixture of lidocaine prilocaine and 2 is lubricants.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
A B C code is required for each group. At night the technician (blind to AB groups) contact the code holder who is blind to each of the groups (CAB), to be informed for titration in order to use the gel in 1 or 2 or he should not use the gel. It should be explained that in Group C no gel 1 or 2 is used, it is not possible to blind technicians and patients in this group. The technician and the patient are blind to the type of material used. Gel 1 is a mixture of lidocaine prilocaine and 2 is lubricants.

**Placebo**

Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**  
1

**Ethics committee**  
**Name of ethics committee**  
 Vice-Chancellor in Research Affairs- Tehran University of Medical Sciences  
**Street address**  
 Baharloo Hospital, Behdari St, Railway Sq, and Tehran, Iran  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 12299  
**Approval date**  
 2019-09-21, 1398/06/30  
**Ethics committee reference number**  
 IR.TUMS.VCR.REC.1398.552

## Health conditions studied

1

**Description of health condition studied**  
Obstructive sleep apnea

**ICD-10 code**  
G47.33

**ICD-10 code description**  
G47.33

## Primary outcomes

1

**Description**  
comfortably of CPAP mask usage

**Timepoint**  
Two times, immediately after putting CPAP mask and 15 minutes after applying gel

**Method of measurement**  
Visual analogue scale

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Patients who candidates for CPAP titration due to obstructive sleep apnea

### Category

Treatment - Devices

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Baharlou hospital

#### Full name of responsible person

Reza Erfanian Azimzadeh Khosravi

#### Street address

Baharloo Hospital, Behdari St, Railway Sq, and Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

12299

#### Phone

+98 21 5565 8500

#### Email

Hosp\_baharloo@tums.ac.ir

## 2

### Recruitment center

#### Name of recruitment center

Imam Khomeini Hospital complex

#### Full name of responsible person

Reza Erfanian Azimzadeh Khosravi

#### Street address

Imam Khomeini Hospital Complex, End of Keshavarz Blvd

#### City

Tehran

#### Province

Tehran

#### Postal code

419733141

#### Phone

+98 21 6658 1587

#### Email

Imamhospital@tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohammad Ali Sahraian

#### Street address

Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Phone

+98 21 81631

#### Email

tums\_edu@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

#### Full name of responsible person

Reza Erfanian Azimzadeh Khosravi

#### Position

Assistant Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Ear, Nose, and Throat

#### Street address

Sa'adi Shomali Street, Darwazeh Doulat, the new building of Amir Alam Hospital

#### City

Tehran

#### Province

Tehran

#### Postal code

1145755811

#### Phone

+98 21 6670 6106

#### Email

rezakhosravimd@gmail.com

## Person responsible for scientific

## inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Reza Erfanian Azimzadeh Khosravi

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is 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**

Part of data would be accessible

**When the data will become available and for how long**

In time of publishing the results

**To whom data/document is available**

Researchers in the field of sleep medicine

**Under which criteria data/document could be used**

For helping to treat sleep disorders

**From where data/document is obtainable**

Dr Reza Erfanian rezakhosravimd@gmail.com

**What processes are involved for a request to access data/document**

At end of the project by email

**Comments**