Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 2) 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)

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+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 refeered 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
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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
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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
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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
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Person responsible for scientific

inquiries

Contact

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Full name of responsible person
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Position
Assistant Professor

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Assistant Professor

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Postal code
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Phone
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Email
rezakhosravimd@gmail.com

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 rezakhoravimd@gmail.com

What processes are involved for a request to access data/document
At end of the project by email

Comments