Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative analysis between the result of treatment with daily titrated Pap-therapy and nightly titrated Pap-therapy in OHS patient

Protocol summary

Study aim
A comparative analysis between the result of treatment with daily titrated Pap-therapy and nightly titrated Pap-therapy in OHS patient
Design
A clinical trial with parallel groups on 122 patients randomized by random numbers table.
Settings and conduct
Patients were randomly divided in two groups and treated with daily & nightly positive airway pressure (PAP) therapy. Participants were blinded. This study was done in Isfahan city.
Participants/Inclusion and exclusion criteria
Inclusion criteria: patients known for obesity hypoventilation syndrome (OHS) with the age of 18 years old or more. Exclusion criteria: Chronic obstructive pulmonary disease (COPD), Interstitial lung disease (ILD), Scoliosis
Intervention groups
Daily titrated positive airway pressure (PAP) therapy group and Nightly titrated airway pressure (PAP) therapy group
Main outcome variables
Evaluation and comparison of mean blood O2-saturation, Evaluation and comparison of mean score of ESS questionnaire, Evaluation and comparison of mean pressure of blood Co2

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170512033930N2**
Registration date: **2021-12-02, 1400/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-02, 1400/09/11**
Update count: **0**
Registration date
2021-12-02, 1400/09/11

Registrant information
Name
Forogh Soltaninejad
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 3224 0059
Email address
f.soltaninejad@med.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-22, 1400/09/01
Expected recruitment end date
2022-03-20, 1400/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative analysis between the result of treatment with daily titrated Pap-therapy and nightly titrated Pap-therapy in OHS patient

Public title
A comparison between the result of daily and nightly titrated Pap-therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Obesity hypoventilation syndrome (OHS) patient Adult older than 18 Patients without COPD Patients without restrictive lung disease Patients without problems of chest wall BMI greater than 35 Paco2>45

Exclusion criteria:

Patients with known COPD Scoliosis Patients with known restrictive lung disease Patient younger than 18 congestive heart failure (EF<40%) Fev1/FVC< 70

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through block method. There are 8 blocks that each one have 4 members for night groups and 4 members for day groups. For better working EPI-INFO-7 software will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

thics committee of Isfahan University of Medical Sciences

Street address

Shams Abadi street

City

Isfahan

Province

Isfehan

Postal code

8135613193

Approval date

2020-03-30, 1399/01/11

Ethics committee reference number

IR.MUI.MED.REC.1399.008

Health conditions studied

1

Description of health condition studied

Obesity Hypoventilation syndrome (OHS)

ICD-10 code

E66.2

ICD-10 code description

Extreme obesity with alveolar hypoventilation

Primary outcomes

1

Description

Co2 pressure (pco2)

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

By capnograph

2

Description

O2 saturation

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

By pulse oximeter

3

Description

Epworth Sleepiness Scale score

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

By Epworth Sleepiness Scale

Secondary outcomes

empty

Intervention groups

1

Description

Treatment with daily titrated positive airway pressure with Bipap or Cpap device manufactured by ResMed company for at least 4 hours in one day in a period of 12 weeks

Category

Treatment - Devices

2

Description

Treatment with nightly titrated positive airway pressure with Bipap or Cpap device manufactured by ResMed for at least 4 hours in one day in a period of 12 weeks

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Bamdad Medical Clinic Center
Full name of responsible person
Marzieh Ghasemi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Foroogh Soltaninejad
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available