

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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)

Phone

+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

Isfahan

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

Street address

Sheikh Mofid Ave

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8156163161

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Foroogh Soltaninejad

Street address

Hezar Jarib Ave

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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 scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Associate professor

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Person responsible for updating data

Contact

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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