

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the Effect of Non-Invasive Ventilation on Depression in Patients with Obesity Hypoventilation Syndrome

Protocol summary

Study aim

Assessing patients with obesity hypoventilation syndrome using depression questionnaire and the impact of non-invasive ventilation on it

Design

Clinical trial without control group, phase 2 on 50 patients

Settings and conduct

The study will be conducted in Isfahan and Khorshid Hospital on patients with low-risk obesity syndrome who are candidates for non-invasive ventilation. Patients will be tested for blood gases and a depression questionnaire before and after non-invasive ventilation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Having low-risk obesity syndrome 2) Patient satisfaction with non-invasive ventilation 3) Confirmation of patients' depression by a psychiatrist. Exclusion criteria: 1) death before the end of the study 2) Dissatisfaction of the patient to complete the study

Intervention groups

Intervention group: Patients are hospitalized for sleep test. Meanwhile, checklists for the Depression Questionnaire will be collected before the non-invasive ventilation and one month after the procedure. Diagnosis of depression in patients during the relevant tests is done using questionnaires and approved by a psychiatrist. Before treatment and also one month after non-invasive ventilation treatment, patients' blood gases are measured. In the invasive ventilator method, the patient's breathing is supported by the CPAP, which is connected to a mask, and helps the patient to breathe effectively. In these patients, there is a gradual improvement in daily performance and good night's sleep, and in many cases even proper weight gain occurs, so the patient gradually comes to the conclusion that he himself tends to use NIV. In this method, the pressure starts from 4 to 6 CmH₂O and increases to 10 or even more if needed.

Main outcome variables

The severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200702047987N1**

Registration date: **2020-07-08, 1399/04/18**

Registration timing: **prospective**

Last update: **2020-07-08, 1399/04/18**

Update count: **0**

Registration date

2020-07-08, 1399/04/18

Registrant information

Name

Zohre Naderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0682

Email address

zo698@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-20, 1399/05/30

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effect of Non-Invasive Ventilation on Depression in Patients with Obesity Hypoventilation Syndrome

Public title
The impact of non-invasive ventilation on Obesity hypoventilation syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having obesity hypoventilation syndrome Patient' will for non-invasive ventilation Confirmation of patients' depression by a psychiatrist
Exclusion criteria:
Death before completing the study Dissatisfaction of the patient to complete the study

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-06-15, 1399/03/26

Ethics committee reference number

IR.MUI.MED.REC.1399.232

Health conditions studied

1

Description of health condition studied

obesity hypoventilation syndrome

ICD-10 code

G47.36

ICD-10 code description

Sleep related hypoventilation in conditions classified elsewhere

Primary outcomes

1

Description

The severity of depression

Timepoint

Before and one month after the intervention

Method of measurement

Beck Depression Inventory (BDI-II) and Hads Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients are hospitalized for sleep test. Meanwhile, checklists for the Depression Questionnaire will be collected before the non-invasive ventilation and one month after the procedure. Diagnosis of depression in patients during the relevant tests is done using questionnaires and approved by a psychiatrist. Before treatment and also one month after non-invasive ventilation treatment, patients' blood gases are measured by a blood gas test. In the invasive ventilator method, the patient's breathing is supported by the CPAP device, which is connected to the patient by a mask, and helps the patient to breathe effectively. This procedure may be needed first during the patient's sleep at night and eventually with the progression of lung disease during the day. In these patients, there is a gradual improvement in daily performance and good night's sleep, and in many cases even proper weight gain occurs, so the patient gradually comes to the conclusion that he himself tends to use NIV. In this method, the pressure starts from 4 to 6 CmH₂O and increases to 10 or even more if needed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Zohreh Naderi

Street address

Khorshid hospital, Ostandari Ave., Isfahan

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8174673178

Phone

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zo698@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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haghjoo.sh@med.mui.ac.ir

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

Zohreh Naderi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments