Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 IsfahanUniversity of Medical Sciences

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

City
Isfahan

Province
Isfehan

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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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