

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Non-invasive ventilation (NIV) on the body composition and Body Mass Index (BMI) in the patients with obesity hypoventilation (OHS)

Protocol summary

Study aim

Investigation of the effect of Non-invasive ventilation on the body composition and BMI in the patients with OHS (obesity hypoventilation)

Design

Clinical Trial, without control group and without blinding.

Settings and conduct

This study will be conducted on 33 obese patients with hyponatremia. Patients will be selected among the patients in the Isfahan Noor Hospital and will not be blinded due to blindness conditions and there will be no control group. These individuals are analyzed at zero time by the Bioimpedance device in terms of water, protein, fat, and then analyzed again one week, one month, and six months after using BIPAP. In conjunction with the simultaneous analysis of PCO₂ with the aid of a capnograph and O₂Sat The patient's oximeter pulse and BMI are measured. The Bioimpedance is an analytical tool that analyzes and provides information through its own software. The change in weight with oxygen saturation with pulse oximetry and the amount of carbon dioxide through the base of capnography Research shows.

Participants/Inclusion and exclusion criteria

BMI upper than 30 Arterial carbon dioxide upper than 45
Using BIPAP device for the first time

Intervention groups

Patients treated with the BIPAP device developed by Resmed (San Diego, California, United States) for a period of 6 months.

Main outcome variables

The PCO₂ level of the patient's blood BMI Oxygen saturation The patient's body fat The amount of protein in the patient's body The amount of body water in the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N26**

Registration date: **2019-02-26, 1397/12/07**

Registration timing: **prospective**

Last update: **2019-02-26, 1397/12/07**

Update count: **0**

Registration date

2019-02-26, 1397/12/07

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Non-invasive ventilation (NIV) on the body composition and Body Mass Index (BMI) in the patients

with obesity hypoventilation (OHS)

IR.MUI.REC.1396.3.186

Public title

The effect of Non-invasive ventilation (NIV) on the body composition and Body Mass Index (BMI) in the patients with obesity hypoventilation (OHS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

BMI upper than 30 Arterial carbon dioxide upper than 45
Using BIPAP device for the first time

Exclusion criteria:

Asthma Obstructive Pulmonary Disease Heart Failure
Pregnancy Using weight loss drugs Using Corticosteroids
Drugs

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 33

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 Jareeb
street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2017-05-17, 1396/02/27

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Extreme obesity with alveolar hypoventilation

ICD-10 code

E66.2

ICD-10 code description

Morbid (severe) obesity with alveolar hypoventilation

Primary outcomes

1

Description

Body water of patient

Timepoint

Begin of studying then one week, one month and six
months

Method of measurement

With the help of Bioimpedance analyzer

2

Description

Body protein of patient

Timepoint

Begin of studying then one week, one month and six
months

Method of measurement

With the help of Bioimpedance analyzer

3

Description

Body fat of patient

Timepoint

Begin of studying then one week, one month and six
months

Method of measurement

With the help of Bioimpedance analyzer

4

Description

Blood PCO2 of patient

Timepoint

Begin of studying then one week, one month and six
months

Method of measurement

Capnography

5

Description

Body Mass Index (BMI)

Timepoint

Begin of studying then one week, one month and six
months

Method of measurement

Using the balance, the weight of the patient will be measure and by using meter the height of patient will be measure

6

Description

O2 saturation

Timepoint

Begin of studying then one week, one month and six months

Method of measurement

Pulse Oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who first time use BIPAP. The patients will use BIPAP device during sleep. The BIPAP device that will be used is RESMED lumis 100 (produced by RESMED company San Diego, California, US)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Pulmonary Disease Clinic of Noor Hospital

Full name of responsible person

Dr. Babak Amra

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Isfahan, Ostandari Street, Pulmonary Disease Clinic of Noor Hospital, Noor Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoye Javanmard

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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

Dr. Babak Amra

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Latest degree

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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

whole data will be available.

When the data will become available and for how long

Immediately after publishing the manuscript of research

To whom data/document is available

All person who need this data

Under which criteria data/document could be used

All person who need this data

From where data/document is obtainable

Dr Amra, University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

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

Sending an email to Amrababak@gmail.com. Data will send shortest possible time

Comments