Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
his study will be conducted on 33 obese patients with hyponatreation. 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
Iran (Islamic Republic of)

Phone
+98 31 3629 1510

Email address
mehrabi@mui.ac.ir

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)

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
Isfehan
Postal code
8174675731
Approval date
2017-05-17, 1396/02/27
Ethics committee reference number
IR.MUI.REC.1396.3.186

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 Oximetery

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
Street address
Isfahan, Ostandari Street, Pulmonary Disease Clinic of Noor Hospital, Noor Hospital
City
Isfahan
Province
Isfehan
Postal code
8771869467
Phone
+98 31 5743 7144
Email
Amrababak@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Haghjoye Javanmard
Street address
Isfahan University of Medical Sciences, Hezar jareeb street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 5149
Email
sh_haghjoo@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
Dr. Babak Amra
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Isfahan Medical University, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 913 313 9294
Email
Amrababak@gmail.com

Person responsible for scientific 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

Street address
Esfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City
Esfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 913 313 9294

Email
Amrababak@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Babak Amra

Position
Associated Proffessor

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

Street address
Esfahan University ofMedical Sciences, Hezar Jarib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 913 313 9294

Email
Amrababak@gmail.com

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