

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Heart Rate Variability changes by Non Invasive Ventilation in Obesity Hypoventilation Syndrome

Protocol summary

Study aim

Investigating the effect of non-invasive ventilation on the heart rate variability in patients with obesity hypoventilation syndrome

Design

One-blind, clinical trial, 30 patients with obesity hypoventilation syndrome

Settings and conduct

Patients referring to Bamdad respiration research center, if they detect obesity hypoventilation syndrome and fill out the informed consent card and have criteria for entering the study, are monitored and cardiac heart rate data are collected for each patient separately. At least Three months after treatment, patients will again undergo Holtermonitoring and data on heart changes will be collected. Then, the results of Holtermonitoring before and after treatment, will be analyzed by appropriate statistical software.

Participants/Inclusion and exclusion criteria

Entry requirements include recent diagnoses of obesity-induced hypoventilation, provided that hypoventilations are not caused by renal failure, hypothyroidism, central hypoventilation. Conditions for not admitting to the study include those who do not complete the informed consent.

Intervention groups

The intervention group includes patients who have recently been diagnosed with obesity hypoventilation syndrome and are undergoing heart rate changes through Holter monitoring before and after treatment with noninvasive ventilation

Main outcome variables

Early diagnosis of cardiac complications due to Hypoventilation syndrome; Statistical analysis of the relationship between heart rate variability and ventilation functions.

General information

Reason for update

Acronym

Heart Rate Variability

IRCT registration information

IRCT registration number: **IRCT20171219037964N1**

Registration date: **2019-03-15, 1397/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-15, 1397/12/24**

Update count: **0**

Registration date

2019-03-15, 1397/12/24

Registrant information

Name

Babak Amra

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

amra@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Heart Rate Variability changes by Non Invasive Ventilation in Obesity Hypoventilation Syndrome

Public title

The effect of noninvasive ventilation on heart rate variability in patients with obesity hypoventilation syndrome

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with obesity hypoventilation syndrome

Exclusion criteria:

Central hypoventilation renal failure Hypothyroidism

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Each patient is included in the study individually and after diagnosis, without informing other patients

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

faculty of medicine, Isfahan university of medical sciences, Hezarjereb avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-03-08, 1395/12/18

Ethics committee reference number

IR.MUI.REC.1396.3.185

Health conditions studied**1****Description of health condition studied**

Obesity Hypoventilation Syndrome

ICD-10 code

E66.2

ICD-10 code description

Morbid (severe) obesity with alveolar hypoventilation

Primary outcomes**1****Description**

Heart Rate Variability

Timepoint

Before treatment, and at least 3 months after using noninvasive ventilation

Method of measurement

Holter monitoring

Secondary outcomes

empty

Intervention groups**1****Description**

Patients after the diagnosis of hypoventilation syndrome of obesity and, if there are criteria for entry into the study, are subjected to the study of the change in heart rate by Holter monitoring. After receiving at least three months of non-invasive ventilation therapy, they will be re-evaluated for heart rate variability and the data will be compared with each other.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bamdad Respiratory Research Center

Full name of responsible person

Babak Amra

Street address

No. 11, Sheikh-e-mofid street, North Sheikh-e-sadoogh avenue

City

Isfahan

Province

Isfahan
Postal code
8146111111
Phone
+98 31 3663 7177
Email
amra@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Faculty of medicine, Isfahan university of medical sciences, Hezarjerib avenue
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0048
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
Babak Amra
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Respiratory Disease_Sleep

Street address

Faculty of medicine, Isfahan university of medical sciences, Hezarjerib avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

amra@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Babak Amra
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Respiratory disease_Sleep
Street address
Faculty of medicine, Isfahan university of medical sciences, Hezarjerib Avenue
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
amra@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Babak Amra
Position
Professor
Latest degree
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Respiratory disease_ sleep
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Hezarjerib Avenue
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more data is available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available