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Ventilation therapy supports heart functioning in obese people with respiratory failure

Submission date
21/06/2024

Recruitment status
No longer recruiting

Registration date
18/07/2024

Overall study status
Completed

Last Edited
18/07/2024

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In patients with obesity hypoventilation syndrome (OHS), a condition in which severely overweight people fail to breathe rapidly or deeply enough, breathing support with ventilation therapy has been shown to improve blood pressure in the lung circulation and improve some heart functions as well. However, it is not yet known if these benefits last over the long term. So, the aim of this study is to examine the long-term effects of a specific type of noninvasive ventilation on heart function and heart-related biomarkers in patients with OHS.

Who can participate?
Clinically stable subjects with obesity hypoventilation syndrome that requires management with ventilation therapy

What does the study involve?
Participants receive standard ventilation treatment for OHS using standardized internationally recommended protocols. Before starting the treatment, they undergo an assessment of their heart function using a novel non-invasive technique that requires the placement of three electrodes on their skin. In addition, blood is drawn to measure parameters that are linked to heart functioning. The same procedures and measurements are repeated after 3 and 12 months of the use of ventilatory support on a daily basis.

What are the possible benefits and risks of participating?
The benefits of participating in the study:
1. Receiving state-of-the-art ventilatory support with regular monitoring and health assessment. This can lead to early detection and management of potential complications, ensuring better health outcomes.
2. Improved symptom control: Ventilatory support is essential for treating respiratory failure and maintaining physiological levels of blood gases in the circulating blood (oxygen and carbon dioxide). Consequently, increased oxygen levels and reduced carbon dioxide levels result in improved control of symptoms such as fatigue, headaches, confusion, cognitive impairment, and /or sleep disturbances.
3. Alleviating obstructive sleep apnea and its symptoms, such as snoring, repetitive multiple breathing cessation during sleep, gasping or choking sensations during sleep, excessive daytime

sleepiness, difficulty concentrating, irritability or mood changes, dry mouth or sore throat upon awakening, restless or unrefreshing sleep, nocturia, decreased libido, and heartburn.
4. Personalized medical attention, ensuring that treatment is tailored to each patient's specific needs, potentially leading to more effective management of their condition. Personalized attention also provides participants with emotional support and practical personalized advice for managing their condition.
5. Enhancing daily functioning and quality of life with important potential long-term benefits: reduced hospitalizations and increased life expectancy.

The risks of participating in the study:
1. Adverse effects associated with ventilatory support: skin irritation and pressure sores resulting from wearing ventilatory masks, nasal dryness and congestion, and gastric distension.
2. Respiratory infections associated with ventilatory support – these are prevented by following stringent hygienic protocols and using disposable ventilatory masks.
3. Sleep disruption in case of discomfort or poor fit related to ventilation masks or the noise from the ventilatory devices – these are prevented by diligent observation and monitoring by a trained certified sleep technician during the introduction of noninvasive ventilation. Should any of these occur, adjustments are made to the ventilation mask and interface.
4. Discomfort during the impedance cardiography measurements resulting from lying on your back throughout the procedure.
5. Risks related to blood draws: local discomfort, bruising, or infection at the puncture site.

Where is the study run from?
PJ Safarik University, Kosice, and L Pasteur University Hospital in Kosice (Slovakia)

When is the study starting and how long is it expected to run for?
March 2016 to November 2019

Who is funding the study?
Slovak Research and Development Agency under contract No. APVV-16-0158, and VEGA 1/0220 /17 and 1/0393/22 of the Ministry of Education (Slovakia)

Who is the main contact?
1. Dr Pavol Pobeha, pavol.pobeha@upjs.sk
2. Dr Ivana Paranicova, ivana.paranicova@upjs.sk

Contact information

Type(s)
Principal investigator

Contact name
Dr Pavol Pobeha

ORCID ID
https://orcid.org/0000-0003-3074-867X

Contact details
Rastislavova 43
Kosice
Slovakia

04190
+421 (0)556152642
pavol.pobeha@upjs.sk

Type(s)
Scientific

Contact name
Dr Ivana Paranicova

ORCID ID
https://orcid.org/0000-0003-1774-6653

Contact details
Rastislavova 43
Kosice
Slovakia
04190
+421 (0)556152642
ivana.paranicova@upjs.sk

Type(s)
Public

Contact name
Dr Pavol Pobeha

ORCID ID
https://orcid.org/0000-0003-3074-867X

Contact details
Rastislavova 43
Kosice
Slovakia
04190
+421 (0)556152642
pavol.pobeha@upjs.sk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2016/EK/3003

Study information

Scientific Title

Long-term myocardial effects of noninvasive ventilation in patients with obesity hypoventilation syndrome

Study objectives
Chronic effects of noninvasive ventilation (NIV) on myocardial function in patients with obesity hypoventilation syndrome (OHS) are scarcely understood. The aim of the present study is to evaluate the long-term effects of volume-targeted bilevel-positive airway pressure ventilation (BiPAP) on cardiac parameters and myocardial biomarkers in patients with OHS.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/03/2016, Ethics committee of L. Pasteur University Hospital (Rastislavova 43, Košice, 04190, Slovakia; +421 (0)55 615 2642; eticka.komisia@unlp.sk), ref: 2016/EK/3003

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Other, Treatment, Safety

Health condition(s) or problem(s) studied
Obesity hypoventilation syndrome, chronic hypercapnic respiratory failure

Interventions
At baseline, all patients were assessed for meeting the inclusion criteria, including history, physical examination, anthropometry, transthoracic echocardiography (Aloka, Tokyo, Japan), spirometry (Ganshorn PowerCube, LF8.5F Release 2), and blood gas analysis. All eligible subjects then underwent a sleep study, ICG, and blood sampling for biomarkers assessment. BiPAP therapy was initiated and patients were instructed to use BiPAP at home every night and also while napping during the daytime. Repeated ICG assessment and blood sample analyses were performed after 3 and 12 months of home-based BiPAP use. The nightly use of BiPAP was evaluated by software analysis embedded in the ventilators. Compliance with BiPAP therapy was deemed sufficient when the patient used the ventilator on average for >4 hours/night.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Noninvasive ventilation, bilevel positive airway pressure, specifically Lowenstein Prisma 30ST

Primary outcome(s)

Cardiac output (in litres per minute), stroke volume (in milliliters), and heart rate (in beats per minute) measured by impedance cardiography (ICG) at baseline, and after 3 and 12 months of using noninvasive ventilation for treatment of chronic respiratory failure

Key secondary outcome(s))
Biochemical markers analysed in venous blood: serum troponin 1 (pg/ml), N-terminal pro-B-type natriuretic peptide (pg/ml), tumor necrosis factor-alpha (pg/ml), and interleukin-6 (pg/ml), measured at baseline, and after 3 and 12 months of using non-invasive ventilation for treatment of chronic respiratory failure

Completion date
15/11/2019

Eligibility

Key inclusion criteria
1. Clinically stable patients with OHS and severe hypercapnia during the daytime
2. Referred to the tertiary clinic for the initiation of long-term NIV to alleviate chronic respiratory failure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
80 years

Sex
All

Total final enrolment
13

Key exclusion criteria
1. Inability to provide written informed consent
2. Neuromuscular, chest wall, or metabolic disease resulting in hypercapnia
3. Acute respiratory tract infection
4. Chronic obstructive pulmonary disease (COPD)
5. Systolic LV failure as evidenced by LV ejection fraction <45% on transthoracic echocardiography

Date of first enrolment
01/06/2016

Date of final enrolment
15/10/2018

Locations

Countries of recruitment
Slovakia

Study participating centre
Department of Respiratory Medicine and Tuberculosis, Pavol Jozef Safarik University, Medical Faculty and L. Pasteur University Hospital In Kosice
Rastislavova 43
Kosice
Slovakia
04190

Sponsor information

Organisation
University of Pavol Jozef Šafárik

ROR
https://ror.org/039965637

Funder(s)

Funder type
Government

Funder Name
Vedecká Grantová Agentúra MŠVVaŠ SR a SAV

Alternative Name(s)
Scientific Grant Agency, VEGA

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
Slovakia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Ivana Paranicova (ivana.paranicova@upjs.sk).
The type of data that will be shared: data spreadsheets for all parameters recorded during impedance cardiography; biochemical parameters, demographics.
The researchers anonymized data using a combination of techniques to protect individual privacy while maintaining the utility of the data for research purposes, following established guidelines and best practices (General Data Protection Regulation [GDPR] for personal data in the European Union). They removed direct and/or specific identifiers from all research databases, such as names, social security numbers, email addresses, residential addresses, phone numbers, and medical record numbers, and birthdates. Unique codes were assigned to each participant instead of using their names. The Ethics Committee of the Faculty of Medicine, PJ Safarik University in Kosice, Slovakia (https://www.upjs.sk/app/uploads/sites/9/2023/09/Statut_EK_UPJS_LF_2007_ENG.pdf) raised no ethical or legal concerns or restrictions.

IPD sharing plan summary
Available on request