Treatment of sleep-disordered breathing with predominant central sleep apnoea by adaptive servo ventilation in patients with heart failure (Major Substudy of SERVE-HF)

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To assess changes in left ventricular performance using echocardiography as well as ventricular remodelling, changes in sleep and changes in mood, anxiety and cognitive functions occurring as a result of treatment of predominant central sleep apnoea...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37747

Source
ToetsingOnline

Brief title
SERVE-HF major substudy

Condition

- Other condition
- Heart failures

Synonym
central sleep apnea, heart failure

Health condition

sleep disordered breathing, predominantly central sleep apnea syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Europe ResMed Germany Inc
Source(s) of monetary or material Support: ResMed

Intervention

Keyword: heart failure, quality of life, sleep disordered breathing, ventricular function

Outcome measures

Primary outcome

The primary endpoint is the change in LV ejection fraction (EF), as measured by Echocardiography, from baseline to 12 months comparing patients randomised to ASV (in addition to optimal medical therapy) with those randomised to continue with optimal medical therapy alone.

Secondary outcome

• Changes in left and right ventricular function

• Changes in LV systolic and diastolic indexed volumes

• Changes in right ventricular (RV) systolic and diastolic indexed volumes

• Changes in LV and RV mass

• Changes in LV sphericity index and LV end-systolic global wall stress

• Changes in sleep duration and sleep stages as well as arousals

• Changes in sleep-disordered breathing

• Changes in quality of life assessed by Kansas City Cardiomyopathy Questionnaire (KCCQ)

• Changes in mental status assessed by Mini-Mental State Examination (MMSE)

• Changes in Patient Health Questionnaire-9 (PHQ-9) score and Patient Anxiety

Study description

Background summary

This protocol describes a substudy within the SERVE-HF programme, designed to evaluate the impact of ASV on left ventricular remodelling and examine the relationship between this and control of SDB and sleep quality. Additionally changes in cognitive function, depression and anxiety will be investigated. Adaptive servo-ventilation (ASV), a specific type of non-invasive ventilation, ameliorates central sleep apnea (CSA) and by controlling sleep-disordered breathing reduces arousals and sleep fragmentation, sympathetic stress and normalizes oxygenation during sleep.

Study objective

To assess changes in left ventricular performance using echocardiography as well as ventricular remodelling, changes in sleep and changes in mood, anxiety and cognitive functions occurring as a result of treatment of predominant central sleep apnoea by adaptive servoventilation in chronic heart failure in addition to optimal medical therapy in chronic heart failure. This will be a substudy of the SERVE-HF study.

Study design

This substudy is performed within the SERVE-HF Study, a randomised, multi-centre, international trial with parallel group design, with patients randomised to either control (optimal medical management) or active treatment (optimal medical treatment plus use of adaptive servoventilation) in a 1:1 ratio. The randomization will be the same as in the parent study. For this purpose, the randomization of the parent study will be stratified as to whether a patient is included in the substudy or not.

Intervention

see for more information ABR form SERVE-HF

Study burden and risks

MRI scans are commonly performed and are generally safe. Some people may find being inside the scanner slightly claustrophobic. The radiowaves used in MRI can heat body tissues and metals. Increased body temperature may cause problems

in certain people. There is a slight poosibility of getting burnt if one comes into contact with metal objects, such as metal in clothing or equipment. Contact between the limbs can also create a burn and foam pads may be placed between the limbs so that this doesn't happen.
If there are metal fillings in the teeth the patient may also feel a tingling in the teeth during the scan, but this does not damage the teeth.
No additional blood tests will be taken in this substudy. Instead some extra tests will be done on the blood we take from the patient in the main study. The Blood tests will involve taking some blood from a vein in the arm and these can occasionally be uncomfortable and sometimes people are left with a bruise. Very occasionally people feel a little light headed when they have a blood sample taken.
There are no side effects of Echocardiography nor of sleep studies.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The inclusion criteria for the parent SERVE-HF Study apply to the sub-study:
• Patient must be at least 22 years old
• Chronic heart failure (at least 12 weeks since diagnosis) according to the currently applicable guidelines
• LVEF <= 45% by imaging method such as echocardiography, radionuclide angiography, left ventriculography, or cMRI documented less than 12 weeks before randomization
• NYHA Class III or IV at the time of inclusion or NYHA Class II with at least one hospitalization for heart failure in the last 24 months.
• No hospitalization for heart failure for at least 4 weeks prior to inclusion
• Optimised medical treatment according to applicable guidelines, with no new class of disease modifying drug for more than 4 weeks prior to randomization. In case of no beta blockers or ACE inhibitors/ARB antagonists the reasons must be documented.
• Predominant central sleep apnoea (apnoea hypopnoea index > 15/hour with >= 50% central events and a central AHI >=10/hour, derived from polygraphy or polysomnography (based on total recording time), documented less than 4 weeks before randomization. Flow measurements to be performed with nasal cannula.
• Patient is able to understand fully the study information and to provide signed informed consent
Additional inclusion criteria for the substudy
• Patients must be at least 22 years old
• Predominant central sleep apnoea (apnoea hypopnoea index > 15/hour with >= 50% central events and a central AHI >=10/hour, derived from full polysomnography (based on total sleep time), documented less than 4 weeks before randomization. Flow measurements to be performed with nasal cannula

Exclusion criteria

Patient Exclusion Criteria of the Parent Study
Patients will not fulfil any of the parent SERVE-HF Study exclusion criteria:
• Significant chronic obstructive pulmonary disease with forced expiratory volume within one second < 50% of age and gender normal values, in the last 4 weeks before randomization
• Oxygen saturation at rest during the day <= 90% at inclusion
• Current use of positive airways pressure
• Life expectancy < 1 year for disease unrelated to chronic heart failure
• Cardiac surgery, percutaneous coronary intervention, myocardial infarction or unstable angina within 6 months prior to randomization
• CRT-implantation (either CRT-D or CRT-P) scheduled or within 6 months prior to randomization
• Transient ischaemic attack or stroke within 3 months prior to randomization
• Primary haemodynamically significant uncorrected valvular heart disease, obstructive or regurgitant, or any valvular disease expected to lead to surgery during the trial
• Acute myocarditis/pericarditis within 6 months prior to randomization

• Untreated or therapy refractory Restless Leg Syndrome
• Patients for whom the use of AutoSet CS / S9 VPAP Adapt may be contra-indicated according to the user*s manual of the device used
• Pregnancy
Additional exclusion criteria for the substudy
• Amyloidosis, hypertrophic obstructive cardiomyopathy or arteriovenous fistulas
• Dosage changes of diuretics more than doubled within the last 4 weeks prior to randomization

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2012
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	adaptive servo-ventilation ASV AutoSet CS
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01164592
CCMO	NL39176.042.11