Prevalence of Sleep Apnea Syndrome in patients with stable Chronic Heart Failure in the Dutch population

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1. To assess prevalence of SAS in a Dutch chronic heart failure (CHF) population. 2. To assess whether there are group differences between CHF-patients without SAS and CHF-patients with SAS (OSAS and CSAS). 3. To assess the validity of the ApneaLink...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON35928

Source
ToetsingOnline

Brief title
SAS in CHF

Condition

- Heart failures
- Upper respiratory tract disorders (excl infections)

Synonym
sleep apnea, sleep apnea syndrome (SAS)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: eigen financiële middelen afdeling

Cardiologie

Intervention

Keyword: Chronic heart failure, Prevalence, Risk markers, Sleep apnea syndrome

Outcome measures

Primary outcome

Percentage of CHF-patients without SAS, and percentage of CHF-patients with SAS (OSAS and CSAS). Therefore, apnea-hypopnea index (AHI) will be measured by polysomnography.

Secondary outcome

From online medical patient*s files:

Echocardiographic parameters (i.e. left ventricular ejection fraction),

Parameters of the bicycle ergometric cardiopulmonary exercise test (Peak VO2),

Routine blood measurements (e.g. hemoglobin-level, NT-proBNP).

Additional measurements:

ApneaLink,

Blood sample assessment,

Urine sample assessment,

Excessive Daytime Sleepiness (EDS).

Study description

Background summary

Chronic heart failure (CHF) is a clinical syndrome with a high mortality and morbidity rate, which has a 5-year survival rate of only 50% despite optimal

therapy. Moreover, CHF has a large impact on the quality of life, and leads to high medical costs due to regular hospitalizations. A condition often seen in CHF patients is sleep apnea syndrome (SAS). Sleep apnea can be divided into two forms. Both obstructive sleep apnea syndrome (OSAS) and central sleep apnea syndrome (CSAS) can occur. While SAS affects 2-4% of the middle-aged working population, its prevalence in a CHF population is much higher (50-70%). After adjustment for confounders, patients with both CHF and SAS have a mortality rate twice as high as patients with only CHF. The prevalence of SAS in Dutch patients with CHF is not known at this moment due to a changed medication policy in heart failure. Also, only a few sleep studies are executed in this group of patients.

Study objective

1. To assess prevalence of SAS in a Dutch chronic heart failure (CHF) population. 2. To assess whether there are group differences between CHF-patients without SAS and CHF-patients with SAS (OSAS and CSAS). 3. To assess the validity of the ApneaLink.

Study design

Cross-sectional study. 100 patients with stable CHF will be screened for SAS with polysomnography and the ApneaLink.

Study burden and risks

There is no extra risk or burden as patients with heart failure already will have a blood sample assessment, echocardiogram and a bicycle ergometry test. One of two additions will be a polysomnography+ApneaLink measurement as these patients have a high chance of having SAS (OSAS or CSAS). Also, blood- and urine samples are taken once when patients participate in the study. Venapunction can give some burden as it can give a small local haematoma afterwards. Measuring these parameters will give information about the presence of SAS so that patients can be treated for this disorder when necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Patients with NYHA functional class II-IV stable heart failure for at least 3 months
•Patients able to understand the procedures and are willing to provide informed consent

Exclusion criteria

•Patients aged < 18 years
•Patients who already underwent polysomnography in the previous 12 months
•History of myocardial infarction in the previous 6 months
•History of (minor) stroke in the previous 6 months
•Severe valvular dysfunction
•Severe lung disease (documented COPD GOLD 3 and 4)
•Active and/or treated malignancies within 12 months prior to inclusion
•Patients on cardial resynchronisation therapy (CRT), or scheduled for CRT
•Pregnancy or active breast feeding

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	24-06-2011
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
CCMO	NL35624.042.11