Pathophysiology of Acute Atrial fibrillation in Obstructive Sleep Apnea

Published: 29-07-2020
Last updated: 16-11-2024

The primary objective is to assess the role of obstructive sleep apnea related pathophysiological mechanisms in the initiation of atrial fibrillation by a multi-parametric strategy that combines the estimated parameters. The main hypothesis is that...

Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON54128

Source
ToetsingOnline

Brief title
PARABOLA study

Condition

- Cardiac arrhythmias
- Sleep disturbances (incl subtypes)
- Respiratory disorders NEC

Synonym
atrial arrhythmia, heart rhythm disturbance

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Het Catharina Onderzoeksfonds

Intervention

Keyword: atrial fibrillation, intrathoracic pressure, obstructive sleep apnea, pathophysiology

Outcome measures

Primary outcome

Identification of prognostic factors for the initiation of atrial fibrillation

in relation to obstructive sleep apnea related pathophysiological mechanisms.

Secondary outcome

Validation of nonobtrusive photoplethysmography and diafragm electromyography

measurements as surrogate for invasive esophageal pressure measurement.

Study description

Background summary

Obstructive sleep apnea is a highly prevalent, often undiagnosed, modifiable risk factor for atrial fibrillation, as well as atrial fibrillation related complications and treatment effectiveness. It is unclear which obstructive sleep apnea related pathophysiological mechanism, i.e. intrathoracic pressure shifts, hypoxemia or sympathovagal imbalance, plays the most dominant role, and a better understanding of these mechanisms could provide valuable information in future diagnostic and therapeutic strategies in this population.

Study objective

The primary objective is to assess the role of obstructive sleep apnea related pathophysiological mechanisms in the initiation of atrial fibrillation by a multi-parametric strategy that combines the estimated parameters. The main hypothesis is that intrathoracic pressure fluctuations are the predominant mechanism. The secondary objective is to validate a nonobtrusive sensing technology based on photoplethysmography and diaphragm electromyography measurements as surrogates for gold standard technology based on invasive intraoesophageal pressure measurement.

Study design

An observational study in a selected cohort. Subjects are recruited from the

atrial fibrillation outpatient clinic of the Catharina Hospital, and referred to Kempenhaeghe Centre for Sleep Medicine for a one-night full polysomnography, with the addition of diaphragm electromyography and photoplethysmography. The acquired data will be analysed at the Eindhoven Technical University with the aid of Philips.

Study burden and risks

Screening for obstructive sleep apnea in the atrial fibrillation population is according to the European guidelines, and polysomnography is the gold standard in diagnosing obstructive sleep apnea. The burden and risks associated with participation are few; intraesophageal pressure measurement is the only added burden that could be associated with participation. Although intraesophageal pressure measurement is a part of the regular clinical practice and the gold standard for the measurement of respiratory effort, in daily practice however it is often omitted for various reasons such as cost-perspective, sufficient diagnostic accuracy based on other measurements of respiratory effort or patient comfort. However severe complications are very rare, and no contemporary literature on such complications is published. Minor discomfort might be present, and if needed the intraesophageal catheter can be removed and the polysomnography will be conducted without. As both obstructive sleep apnea and atrial fibrillation are very common, there is a large group that can benefit from the results of this study. The results of this study could create new insights to the treatment of atrial fibrillation and screening for obstructive sleep apnea.

Contacts

Public
Technische Universiteit Eindhoven

Michelangelolaan 2
Eindhoven 5623EJ
NL
Scientific
Technische Universiteit Eindhoven

Michelangelolaan 2
Eindhoven 5623EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Paroxysmal AF, with symptoms occurring at least once per week
STOP-BANG score >=5 or STOP-BANG >=4 and typical nocturnal onset of AF
Ability to provide informed consent

Exclusion criteria

Current (not prior) adequate (i.e. residual AHI <5) treatment with CPAP or MRA
Reversible cause of AF (e.g. hyperthyroidism)
Severe lung disease (COPD Gold IV, pulmonary fibrosis, lobectomy)
Severe esophageal disease (malignancy, stricture, esophagectomy)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-12-2020
Enrollment:	225
Type:	Actual

Medical products/devices used

Generic name:	Gaeltec® CTO-1 single sensor catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-07-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-05-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL73913.100.20