The effect of PSA on the pCO2

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26433

Source
Nationaal Trial Register

Brief title
ECOO

Health condition

Atrial fibrillation

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Radboudumc

Intervention

Outcome measures

Primary outcome

the effects of prolonged deep PSA on the arterial CO2

Secondary outcome

the effects of prolonged deep PSA on the arterial blood gas and pH

Study description

Background summary

Background and study aims:
Atrial fibrillation (AF) is a common sustained rhythm disorder. Pulmonary vein isolation (PVI) is the standard therapeutic treatment for symptomatic AF.
This procedure may cause discomfort to the patient.
Therefore, PVI is usually performed under procedural sedation and analgesia (PSA).
PSA is associated with respiratory depression which leads to alveolar hypoventilation and resultating in increased arterial CO2 levels.
There is no data available regarding the actual effect of PSA on the arterial CO2 and the blood gas.
We hypothesize that prolonged deep PSA increases the arterial CO2 levels. Increased levels of CO2 lead to a change in the pH of the blood, i.e. a respiratory acidosis. Although there are no obvious adverse effects of short-term acidosis, it is not a physiologically normal condition.

study population:
Patients between 18 and 80 years, which are scheduled for a pulmonary vein isolation with PSA and is willing to participatie in this trail.

what does the study involve?
Patients who are included in the study will get an arterial catheter prior to the PSA.
Every 30 minutes a blood samples will be drawn from the catheter to analyse

possible benefits and risks of participating:
There is a minimal risk related to the arterial cannulation. But the incidence is low and arterial cannulation is a relatively safe procedure.
There is no benefit for the patients who participate in the study. The goal is to better understand the side effects of PSA

Study objective

We hypothesize that prolonged deep PSA increases the arterial CO2 levels

Study design

start just before the pulmonale vein isolation and end 60 minutes after the procedure.

Intervention

none

Contacts

Public
radboudumc
Twan Aalbers

0243614406
Scientific
radboudumc
Twan Aalbers

0243614406

Eligibility criteria

Inclusion criteria

1. Pulmonary vein isolation performed under PSA
2. Age 18-80 years
3. ASA classification 1 or 2
4. Informed consent

Exclusion criteria

1. Pregnancy
2. BMI >30
3. BMI <18
4. Obstructive sleep apnea syndrome
5. COPD / Astma
6. Known bleeding disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46065
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7812
CCMO	NL67983.091.18

Register	ID
OMON	NL-OMON46065

Study results