Study: The effect of PSA on the pCO2

Published: 09-05-2019
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In this study we want to show what the consequences are of the respiratory depression that accompanies prolonged PSA

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

Summary

ID

NL-OMON46065

Source
ToetsingOnline

Brief title
ECOO

Condition

- Other condition

Synonym
procedurele sedatie en analgesie

Health condition

procedurele sedatie en analgesie (PSA)

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CO2, procedural sedation and analgesia, pulmonary vein isolation

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the effects of prolonged

deep PSA on the arterial CO2.

Secondary outcome

The secondary objective if this study is to evaluate the effects of prolonged

deep PSA on the arterial blood gas and pH.

Study description

Background summary

Atrial fibrillation (AF) is a common sustained rhythm disorder and pulmonary vein isolation (PVI) is the standard therapeutic treatment for symptomatic AF2. This procedure takes a longer period of time and may cause discomfort to the patient.
Therefore, PVI is usually performed under procedural anesthesia and analgesia (PSA).
PSA is be associated with respiratory depression which leads to alveolar hypoventilation and resultating in increased arterial CO2 levels.
There is no data available what the actual effect of PSA on the arterial CO2 and the blood gas is.
We hypothesize that prolonged deep PSA increases the arterial CO2 levels.

Study objective

In this study we want to show what the consequences are of the respiratory depression that accompanies prolonged PSA

Study design

single centre prospective observational study

Study burden and risks

Patient who are included in the study will get an arterial catheter prior to the PSA.
Depending on the duration of the procedure, a numer of blood samples are taken from the catheter to analyse. All other measurement and treatment to the patients are part of standard care.
Patients have al little risk of incidence related to the arterial cannulation. But the incidence is rare and the arterial cannulation is a relatively safe procedure.

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, ASA 1-2, between 18 and 80 years, which are scheduled for a pulmonary vein isolation performed with PSA.

Exclusion criteria

Pregnancy
BMI >30
BMI <18
Obstructive sleep apnea syndrome
COPD / Astma

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	09-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26433
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67983.091.18
OMON	NL-OMON26433