High Flow Nasal Cannula versus Low Flow Nasal Cannula in patienst with atrial fibrillation undergoing point-by-point catheter ablation under deep sedation.

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To test the effect and incidence of hypoxemia when oxygen supplementation through HFNC as compared to LFNC in patients with atrial fibrillation undergoing point-by-point ablation (like RFCA or Galaxy PFA) and deep sedation.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52794

Source
ToetsingOnline

Brief title
HFNC vs LFNC in patients with AF undergoing RFCA/ GPFA under deep sedation.

Condition

- Other condition
- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
desaturation, Hypoxemia

Health condition

Oxygenatie tijdens diepe sedatie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Galaxy Pulse Field Ablation (PFA), High Flow Nasal Cannula, Low Flow Nasal Cannula, Radiofrequency catheter ablation, Sedation

Outcome measures

Primary outcome

Lowest saturation is the measured and main outcome.

Secondary outcome

Secondary objectives of the study are the duration of the lowest SpO2,

incidence of cross over, incidence of desaturation, adverse sedation events,

peak transcutaneous carbon dioxide (TcCO2), mean TcCO2, satisfaction of

patients with sedation, patients comfort with oxygen delivery, rating of

clinician of the anaesthesiology department of difficulty maintaining

oxygenation status, rating of clinician anaesthesiology of user-friendliness of

the oxygen delivery device and satisfaction of cardiologists with catheter

stability in relation to sedation.

Study description

Background summary

Oxygen supplementation through high flow nasal cannula (HFNC) may reduce the incidence of desaturation and hypoxemia during deep sedation at radiofrequency catheter ablation (RFCA procedures).This study is designed to test the

hypothesis that the incidence of hypoxemia and desaturation in patients with atrial fibrillation undergoing point-by-point ablation (like RFCA or Galaxy PFA) under deep sedation, is less when using HFNC as compared to use of standard low flow nasal cannula (LFNC).

Study objective

To test the effect and incidence of hypoxemia when oxygen supplementation through HFNC as compared to LFNC in patients with atrial fibrillation undergoing point-by-point ablation (like RFCA or Galaxy PFA) and deep sedation.

Study design

A randomized controlled trial design is used. Patients will be randomized in a 1:1 ratio to oxygen supplementation through high flow nasal cannula (HFNC) versus standard low flow nasal cannula (LFNC).

Intervention

One group receives HFNC and the other group receives LFNC.

Study burden and risks

The risk to and the burden for the subject is in proportion. LFNC as well HFNC are both used in usual care. The use of HFNC may reduce the incidence of hypoxemia during deep sedation at RFCA procedures. The nasal oxygen canula may cause some discomfort. In addition, a nosebleed can occur, but this is rare. The participant will fill out two questionnaires: Iowa Satisfaction with Anaesthesia Scale (ISAS) and Likert scale on patients comfort with oxygen delivery. The intervention and questionnaires take place during the hospital admission for the RFCA or Galaxy PFA treatment. No other tests or additional site visits are planned.

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

Adults undergoing elective RFCA or Galaxy PFAfor atrial fibrillation in the Maastricht UMC Cardiac Catheter Labs under deep sedation administrated by a clinician anesthesiology.

Exclusion criteria

Age under 18 years
Body Mass Index > 32
Diagnosed sleep apnoea syndrome
Chronic pulmonary obstructive disease gold IV and COPD gold III with recent or frequent exacerbation
Diagnosed pulmonary or cardiac condition requiring chronic oxygen therapy
Complete nasale obstruction
Active nose bleeding
Untreated pneumothorax (pre- existing)
Recent upper airway surgery
Recent base of skull fracture
Expected difficult airway.

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-02-2022
Enrollment:	210
Type:	Actual

Medical products/devices used

Generic name:	Optiflow
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-12-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	23-05-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	28-11-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-07-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL72859.068.20

Study results

Date completed: 18-11-2024

Summary results
Trial ended prematurely