The CAVIAR-trial

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The hypothesis is that minimal invasive surgical ablation through video assisted thoracoscopic surgey as a primary treatment in patients suffering from (longstanding) persistent atrial fibrillation is superior to transvenous catheter ablation

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20520

Bron
Nationaal Trial Register

Verkorte titel
CAVIAR

Aandoening

Persistent and longstanding persistent atrial fibrillation

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: University Medical Center Utrecht (UMCU)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of the study is to evaluate which treatment- surgical ablation or catheter ablation- is most effective in treating persistent and longstanding persistent atrial fibrillation measured by success at 12 months after 1 procedures.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction

Catheter ablation (CA) is a successful treatment option in patients suffering from paroxysmal atrial fibrillation (AF). In patients with (longstanding) persistent AF the results are substantially lower. Over the last years, minimal invasive surgical ablation (SA) through video assisted thoracoscopic surgery (VATS) has been developed. Compared with CA, SA may be more effective, especially after one procedure. No randomized controlled trials directly comparing CA and SA for the primary treatment of (longstanding) persistent AF have been performed yet.

Purpose

The aim of this study is to determine which treatment, SA or CA, is superior as a primary treatment in patients suffering from (longstanding) persistent atrial fibrillation (AF) measured by success at 12 months after 1 procedure

Methods

The CAVIAR-trial is a single center, randomized intervention study with a follow up of 12 months. 60 Patients will be randomized in either:

o Transvenous catheter ablation

o Minimal invasive surgical ablation through video assisted thoracoscopic surgey

The follow-up protocol is the same as standard care. Patients will visit the outpatient clinic at 3, 6, and 12 months post-ablation.

Doel van het onderzoek

The hypothesis is that minimal invasive surgical ablation through video assisted thoracoscopic surgey as a primary treatment in patients suffering from (longstanding) persistent atrial fibrillation is superior to transvenous catheter ablation

Onderzoeksopzet

Follow up will take place at 3,6 and 12 months

Onderzoeksproduct en/of interventie

-Catheter ablation

-Surgical ablation

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients age is > 18 years

- Patients with persistent or longstanding persistent atrial fibrillation. Persistent AF is defined as sustained episodes of atrial fibrillation lasting >7 days. Longstanding persistent AF is defined as sustained episode lasting >1 year.

- Patients undergoing a first time invasive treatment procedure for persistent atrial fibrillation

- AF must be recorded at least once by ECG, holter, telemetry, loop recorder or internal device.

- Patients must give informed consent to participate

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients suffering from paroxysmal atrial fibrillation. Paroxysmal AF is defined as episodes of AF that terminates spontaneously within 7 days.

- Patients suffering from AF secondary to a reversible cause as electrolyte imbalance or hyperthyroidism.

- Body mass index >40

- Active infection or sepsis

- Unstable angina, myocardial infarction within the previous 6 months

- Patients with any contra-indications for electrophysiologic study and ablation in the left atrium:

-pregnancy

-presence of a left atrial thrombus

- Patients with any contra-indications for video assisted thoracoscopic surgery:

- prior lung/cardiac surgery

- pleural adhesions

- elevated hemidiaphragm

- mitral or aortic valve regurgitation above grade 2

- moderate to severe mitral or aortic stenosis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4809
NTR-old	NTR5081
Ander register	ABR : 51954

Resultaten