

Mapping guided Stereotactic ablative Radiotherapy

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Stereotactic radiotherapy of an accurately determined substrate is effective in treating uncontrolled ventricular tachycardia

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

Samenvatting

ID

NL-OMON27436

Bron

NTR

Aandoening

Ventricular tachycardias

Ondersteuning

Primaire sponsor: Departments of Cardiology and Radiotherapy, Leiden University Medical Center

Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- (1) Number of patients in whom the (presumed) clinical VT(s) causing the presenting symptoms can be eliminated (equals: partial success in RFCA studies) for the study period of one year (after 6 weeks blanking).
- (2) Number of patients with the elimination of highly symptomatic VTs (e.g. pre-syncopal VT) or highly symptomatic ICD therapy (e.g. ICD shocks) for the study period of one year (after 6

weeks blanking).

(3) Reduction of any ICD treated VT episodes by $\geq 80\%$ at one year after treatment compared to the year before treatment (including VTs during the 6 weeks blanking)

Toelichting onderzoek

Achtergrond van het onderzoek

Background

Ventricular tachycardias (VT) are a medical emergency and require immediate termination. VT typically occur in patients with a myocardial scar from myocardial infarction or from non-ischemic cardiomyopathies. Despite escalated antiarrhythmic drug (AAD) therapy and advanced catheter ablation technology, up to 50% of patients will experience recurrent VTs. New drugs are not available and current catheter technologies have important and well-recognized limitations in particular to reach deep intramural arrhythmogenic substrates or areas protected by insulated fat or calcification. Despite the availability of state-of-the-art technology and highly experienced operators in tertiary referral centers catheter ablation acutely fails to eliminate the electrical storm causing VTs in 9-12% of the patients. Procedural failure has important prognostic implications during short-term follow-up: sudden death occurs in up to 40% within 3 months despite the ICD, and electrical storm, recurs in almost all. For these patients' therapeutic options to eliminate the VT sources inaccessible by current catheter technologies are urgently needed.

Aim

Treatment of uncontrolled ventricular tachycardia, inaccessible by the current state-of-the-art catheter ablation techniques by using single dose stereotactic radiotherapy of an accurately determined substrate

Doel van het onderzoek

Stereotactic radiotherapy of an accurately determined substrate is effective in treating uncontrolled ventricular tachycardia

Onderzoeksopzet

Patients will receive follow up at 2 weeks, 4 weeks, 12 weeks, 6 months and 12 months after treatment to assess for adverse cardiac effects

Onderzoeksproduct en/of interventie

Stereotactic radiotherapy

Contactpersonen

Publiek

LUMC
Katja Zeppenfeld

00317166933

Wetenschappelijk

LUMC
Katja Zeppenfeld

00317166933

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Age ≥ 18
- Implanted ICD
- Structural heart disease with myocardial scar
- World Health Organization (WHO) / Eastern Cooperative Oncology Group (ECOG) performance status grade 0-3 in the past 3 months, or grade 4 if related to the arrhythmic presentation (from fully active to capable of limited self-care, see below for full explanation)
- Presenting with at least one of the following
 - ☐ Within the past 3 months: electrical storm (defined as ≥ 3 ICD shocks within 24h)
 - ☐ Within the past 3 months: 3 or more episodes of highly symptomatic sustained VT (either requiring ICD shocks, or leading to (pre)syncope)
 - ☐ Recurrent VT (high VT burden) leading to progressive heart failure
 - ☐ Symptomatic, incessant VT not detected by the device or reinitiating after ICD therapy
 - ☐ Progressive heart failure and indication for LVAD, in whom recurrent VT preclude LVAD implantation
- Despite all of the following
 - ☐ Optimal medical treatment according to current guidelines
 - ☐ Failure of recommended antiarrhythmic drugs including failure of amiodarone
 - ☐ Failure of catheter ablation using the current state of the art catheter ablation techniques

to modify the VT substrate

- Able and willing to undergo all necessary evaluations, treatment and follow-up for the study and of follow-up thereafter
- Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Pregnancy
- Interstitial pulmonary disease
- Irreversible renal insufficiency with a glomerular filtration rate $<30\text{ml/min}$ (not related to the high VT burden)
- Life expectancy <12 months in the absence of VT
- Refusal or inability to provide informed consent or to undergo all necessary evaluations, treatment and follow-up for the study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52679

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7950
CCMO	NL70844.058.19
OMON	NL-OMON52679

Resultaten