ELectroanatomic substrate-guided STereotactic Ablative Radiotherapy for refractory Ventricular Tachycardia

Gepubliceerd: 15-03-2021 Laatst bijgewerkt: 18-08-2022

Stereotactic radiotherapy targeting a clearly defined electroanatomic arrhythmogenic substrate is effective and safe in patients with therapy-refractory VT

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

Samenvatting

ID

NL-OMON23673

Bron
NTR

Verkorte titel
ELSTAR-VT

Aandoening

Therapy-refractory VT

Ondersteuning

Primaire sponsor: Departments of Cardiology and Radiotherapy, Maastricht University Medical Centre + & MAASTRO clinic
Overige ondersteuning: MUMC+, STOP-STORM consortium

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of patients with ≥80% reduction of VT burden, i.e., any ICD-treated or highly-symptomatic VT episodes, at one year after STAR compared to the year before (including VTs during the 8 week-blanking period).

Efficacy parameters will be assessed by comparing the 12 months prior to STAR with the 12 months after treatment. All arrhythmic episodes occurring during the blanking period will be collected.

Toelichting onderzoek

Achtergrond van het onderzoek

Ventricular tachycardia (VT) is a life-threatening cardiac arrhythmia that is associated with high mortality and morbidity rates. Unfortunately, current treatment modalities including antiarrhythmic drugs and catheter-based ablation have only limited success. Recent developments consisting of noninvasive stereotactic radiotherapy that specifically targets the arrhythmogenic substrate have emerged to treat VT. In our study we evaluate the efficacy and safety of stereotactic arrhythmia radiotherapy in patients with refractory ventricular tachycardia using high-resolution electroanatomical guidance.

Doel van het onderzoek

Stereotactic radiotherapy targeting a clearly defined electroanatomic arrhythmogenic substrate is effective and safe in patients with therapy-refractory VT

Onderzoeksopzet

Patients will be monitored at day 1, week 1, month 3, month 6, month 9, month 12, month 24 after treatment to assess efficacy and potential adverse effects

Onderzoeksproduct en/of interventie

Electroanatomical characterisation of the arrhythmogenic substrate is achieved by combining 3D-MRI, ECG-imaging and invasive electroanatomical mapping. The VT will be mapped using ECG-imaging during (non)invasive programmed stimulation. Stereotactic radiotherapy will be applied by delivering a single-fraction ablative dose of radiation at the arrhythmogenic substrate.

Contactpersonen

Publiek

Maastricht UMC+
Rachel Ter Bekke

043-3875106

Wetenschappelijk

Maastricht UMC+
Rachel Ter Bekke

043-3875106

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:
• Structural heart disease (ischemic and non-ischemic cardiomyopathy) with myocardial scar and previous ICD implantation.
• 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).
• Recurrent VT
• Despite > 1 prior catheter ablation (last in expert center) with all meaningful mapping/ablation approaches performed (endo/epicardial, LV/RV), a detailed electroanatomical map of substrate and precise image integration available.
OR
• In a patient that is ineligible to undergo invasive catheter ablation (e.g., LV thrombus, double mechanical valves, no vascular access) but with detailed (noninvasive) electroanatomical information and precise image integration available.
• Recurrent VT should be:
• Sustained monomorphic VT, compatible with the arrhythmogenic substrate.
• ≥ 3 VT episodes (syncope, sustained VT, antitachypacing treated or ICD shock) in previous 6 months OR electrical storm (≥ 3 VTs in 24 h) OR symptomatic incessant VT.
• Recorded on 12-lead and compatible with the arrhythmogenic substrate.
• Antiarrhythmic drugs:
• Optimal medical treatment according to current ESC guidelines.
• Failed, intolerance or contraindication to ≥ 1 antiarrhythmic drugs (amiodarone, sotalol, mexiletine, procainamide).
• Patient must be able to understand and be willing to sign an Institutional Review Board

(IRB)-approved written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A patient that meets any of the following criteria will be excluded from participation:
• Age < 18 years.
• Advanced heart failure New York Heart Association (NYHA) class IV or requiring inotropic treatment or mechanical assistance.
• Reversible cause underlying the arrhythmia.
• Interstitial pulmonary disease.
• Acute coronary syndrome, percutaneous coronary intervention or cardiac surgery in last 3 months.
• Life expectancy in absence of VT <12 months.
• Polymorphic VT, torsades de pointes or VF.
• Pregnancy or breastfeeding.
• Overlapping prior radiotherapy to the thoracic region resulting in a cumulative dose that is deemed unsafe by the treating physician.
• Advanced myocardial scar substrate that would require stereotactic delivery to a target volume deemed unsafe by the treating physician.
• Refusal or inability to provide informed consent or to undergo all necessary evaluations, treatment and follow-up for the study.
• Renal insufficiency with a glomerular filtration rate <30ml/min.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2021

Aantal proefpersonen:	23
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

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9339
Ander register	METC MUMC : ABR 77235/NL77235.068.21

Resultaten