ELectroanatomic substrate-guided STereotactic Ablative Radiotherapy for refractory Ventricular Tachycardia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23673

Source
NTR

Brief title
ELSTAR-VT

Health condition

Therapy-refractory VT

Sponsors and support

Primary sponsor: Departments of Cardiology and Radiotherapy, Maastricht University Medical Centre + & MAASTRO clinic
Source(s) of monetary or material Support: MUMC+, STOP-STORM consortium

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Incidence of all-cause mortality and cardiac (non)arrhythmic mortality at 12 and 24 months.
2. Safety: measured by registered adverse events using the CTCAE v5 system, ‘early’ (up to 30 days), ‘intermediate’ (30-90 days), and ‘late’ (>90 days after treatment).
3. Time to first recurrence of sustained VT from in- and outside the STAR-targeted substrate, after 8-week blanking (on the basis of ECG, Holter, ICD readouts).
4. Time to elimination of STAR-targeted VT.
5. Reduction of antiarrhythmic drug use at 12 and 24 months.
6. Elimination and modification of the STAR-targeted arrhythmia substrate as by noninducibility of sustained VT, scar voltage reduction and -inexcitability during invasive electroanatomical evaluation at 6 months.
7. Patient-reported QoL: SF-36, EQ5D.
8. Correlation between target dose-volume parameters to the target and VT number reduction.
9. Correlation between healthy tissue dose-volume parameters and toxicity.
10. Hospitalisation.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	23
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9339
Other	METC MUMC : ABR 77235/NL77235.068.21

Study results