ELectroanatomic substrate-guided STereotactic Ablative Radiotherapy for refractory Ventricular Tachycardia

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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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON51065

Source
ToetsingOnline

Brief title
ELSTAR-VT

Condition

- Cardiac arrhythmias

Synonym
Refractory ventricular tachycardia; malignant cardiac arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: in kind

Intervention

Keyword: Electroanatomic substrate, Stereotactic ablative radiotherapy, Ventricular tachycardia

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

Baseline study parameters such as age, gender, underlying cardiac disease, LV ejection fraction, scar anatomy (3DMRI, electroanatomical map), death, (in)appropriate ICD therapy, antitachypacing, use of antiarrhythmic drugs, target dose-volume parameters, healthy tissue dose-volume parameters, toxicity, quality of life, hospitalisation, ECG-imaging (activation and repolarization times, fragmentation, activation/propagation maps) will be collected and investigated.

Study description

Background summary

Ventricular tachycardia (VT) is a life-threatening cardiac arrhythmia that is

associated with high mortality and morbidity rates. Antiarrhythmic drugs and catheter-based ablation have only limited success, recurrences are frequent. A recent development consisting of noninvasive stereotactic radiotherapy that specifically targets the arrhythmogenic substrate has emerged to treat VT in a small group of patients with therapy-resistant VT. In this study we evaluate the efficacy and safety of stereotactic arrhythmia radiotherapy in patients with refractory ventricular tachycardia using high-resolution electroanatomical guidance.

Study objective

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.

Study design

The stereotactic ablative radiotherapy described in this protocol will be delivered as a one-armed phase II trial to patients. Patients with structural heart disease, a previous ICD implantation, and high burden of VTs are eligible if 1) if the patient is ineligible to undergo invasive catheter ablation or 2) if the VTs are persisting despite anti-arrhythmic drugs and expert catheter ablation. Arrhythmia and safety outcomes will be assessed at 1, 3, 6, 12, and 24 months after treatment aiming to also address long-term results.

Intervention

1. In preparation for stereotactic radioablation:
- Planning-CT
- ECG-imaging.
- SF-36 and EQ5D questionnaires.

2. Stereotactic radioablation with single-fraction ablative dose of radiation.

3. Follow-up STAR (up to 2 years):
- ECG-imaging.
- Cardiac CT.
- (Non) invasive programmed ventricular stimulation and STAR-targeted arrhythmia substrate characterization during invasive electroanatomical evaluation.
- 2D/3D MRI cor (optional).

- SF-36 and EQ5D questionnaires.

Study burden and risks

Study subjects will undergo additional investigations prior to STAR which impose risks:
- Planning CT (including cardiac CT for ECG-imaging): minor risk of allergic reaction to contrast agent or skin electrodes, contrast nephropathy. Anticipated 6-20 mSV.

STAR with a single 25 Gy will last 60 minutes. It is not painful. The intermediate and longterm risks maybe ICD or lead damage, reduction of LVEF, pericardial effusion, long inflammation or coronary damage.

Six months post-STAR a electrostructural evaluation of the radiated area will be performed:
- CT (for pulmonary damage and ECG-imaging): minor risk of allergic reaction to contrast agent or skin electrodes, contrast nephropathy. Anticipated6-20 mSV.
- Cardiac MR: claustrophobia, ICD malfunction, ICD lead heating, allergic reaction to gadolinium.
- Elimination and modification of the STAR-targeted arrhythmia substrate as by noninducibility of sustained VT, scar voltage reduction and -inexcitability during electroanatomical mapping: minor risk of CVA, pericardial effusion, untreatable VT/VF (also during noninvasive programmed electrical stimulation), or, in extreme cases, death.

Benefit:
We anticipate a strong individual benefit of STAR in terms of reduction of VT burden and ICD interventions.

Contacts

Public
Selecteer

P. Debyelaan 25
Maastricht 6202AZ
NL
Scientific
Selecteer

P. Debyelaan 25
Maastricht 6202AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion 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 phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2023
Enrollment:	23
Type:	Actual

Medical products/devices used

Generic name:	Radiotherapy System (TrueBeam;Truebeam STx;Edge) & ECG-imaging Active two
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	31-01-2022
Application type:	First submission
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	NL77235.068.21
Other	NL9339/NL77235.068.21