Mapping guided Stereotactic ablative Radiotherapy

No registrations found.

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

Summary

ID

NL-OMON27436

Source
NTR

Health condition

Ventricular tachycardias

Sponsors and support

Primary sponsor: Departments of Cardiology and Radiotherapy, Leiden University Medical Center
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

(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 ≥80% at one year after treatment compared

to the year before treatment (including VTs during the 6 weeks blanking)

Secondary outcome

(1) Time to elimination of the clinical VT(s) causing symptoms
(2) Time to elimination of any sustained VT/ VT prompting ICD therapy
(3) Elimination of the targeted arrhythmia substrate indicated by absence of inducible sustained VT at 6 months.
(4) Modification of VT substrate indicated by voltage reduction and non-excitability during electroanatomical mapping at 6 months
(5) Number and dosage of class 1 and class 3 AAD at one year
(6) ΔSUVmax on F18-FDG-PET/CT between baseline, 2 weeks and 6 months after treatment.

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

Stereotactic radiotherapy

Contacts

Public
LUMC
Katja Zeppenfeld

00317166933
Scientific
LUMC
Katja Zeppenfeld

00317166933

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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 <30ml/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

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):	01-09-2019
Enrollment:	12
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

ID: 52679
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results