PROspective feasibility study of STereotactic Arrhythmia Radioablation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24469

Source
NTR

Brief title
PRO-STAR

Health condition

Ventriculair tachycardia

Sponsors and support

Primary sponsor: Universitair medisch centrum Utrecht
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

To demonstrate acute safety of delivering STAR. Side effects possibly, probably or definitely related to study treatment are registered conform CTCAE v5.0. The incidence of grade 3 and above toxicity should be ≤ 33.33% within 90 days of treatment.

Secondary outcome

• Reduction in VT burden defined by decline in ICD therapy in shocks and/or ATP compared to the 6 months period prior to STAR (or shorter if ICD information is lacking),
• Changes in antiarrhythmic medication due to treatment effects.
• Changes in patient reported quality of life (recorded as EQ 5D 5L).
• Report late toxicity after 90-days post intervention (according to CTCAE v5.0)

Study description

Background summary

Rationale: Ventricular tachycardia (VT) is a life-threatening heart rhythm disorder. Treatment is possible with anti-arrhythmic drugs, implantable cardioverter-defibrillator and invasive catheter ablations. If VT is refractory to these treatments a single fraction high-dose radiotherapy has recently shown promising results.
Objective: To deliver a single fraction stereotactic radiotherapy with acceptable toxicity and reduction in VT burden.
Study design: Prospective feasibility study
Study population: Eleven patients with therapy refractory VT
Intervention: A single fraction of 25 Gy will be given to the VT substrate. The VT substrate will be defined on an individual patient basis by a clinical cardiac electrophysiologist by combining different (imaging) examinations of the heart. The radiation target will be delineated by the radiation oncologist in consultation with the clinical cardiac electrophysiologist.
Main study endpoints: Acceptable acute toxicity defined by CTCAE v5.0. The incidence of possibly, probably, or definitely treatment related serious adverse events, defined as grade 3 and above) should be <33,33% within 90 days of treatment.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
This study will only include patients refractory to the standard of care for VT. Toxicity due to the stereotactic radiotherapy is the highest risk associated with this treatment. To keep toxicity risk to a minimum, strict dose constraints to the organs at risk (oesophagus, lung, heart, chest wall) will be applied using state of the art planning and treatment procedures. If the dose to the organs at risk is exceeded, the treating radiation therapist should decide if PTV coverage or OAR constraint will be compromised. To investigate quality of life, validated questionnaires will be used.

Study objective

Stereotactic radiotherapy can treat ventriculair tachycardia with acceptable acute toxicity

Study design

Evaluation at 6 weeks, 3, 6 and 12 months after STAR and yearly afterwards

Intervention

Stereotactic radiotherapy

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient must be >18 years old
2. Patient must have therapy refractory VT.
Patient must have failed or become intolerant to at least one antiarrhythmic medication and one invasive catheter ablation procedure or invasive catheter ablation is not possible due to a contraindication (e.g. unfit for general anaesthesia, severe pulmonary disease).
3. Cardiomyopathy, Ischemic or non-ischemic.
4. Patients must have transvenous ICD
5. Patients must have ICD information before study treatment

Exclusion criteria

1. Prior radiotherapy treatment above 30 Gy of the current treatment region
2. Patients must not be pregnant or lactating
3. NYHA class 4
4. Extreme arrhythmia substrate:
a. Polymorphic VT/VF
b. >3 distinct clinical VT morphologies
c. >5 distinct induced VT morphologies during testing
5. The radiotherapy target volume must be suitable for stereotactic radiation.

6. MRI criteria:
a. claustrophobia
b. non-MRI compatible according to https://richtlijn.mijnumc.nl/Beeld/MRI/Documents/Vragenlijst%20MRI-onderzoek%20volwassenen.pdf
7. GFR above 30 ml/min
8. Within one year after heart surgery or placing of an artificial heart valve

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:	Recruiting
Start date (anticipated):	23-09-2021
Enrollment:	11
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
This study will also contribute to the STOPSTORM data registry, where granular data from over 200 patients will be aggregated to fine-tune the treatment.

Ethics review

Positive opinion

Date:	23-09-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51078
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9752
CCMO	NL76535.041.21
OMON	NL-OMON51078

Study results

Summary results
N/A