PROspective feasibility study of STereotactic Arrhythmia Radioablation

Published: 03-05-2021
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To deliver a single fraction stereotactic radiotherapy with acceptable toxicity and reduction in VT burden.

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

Summary

ID

NL-OMON51078

Source
ToetsingOnline

Brief title
PRO-STAR

Condition

- Cardiac arrhythmias

Synonym
ventricular arrhythmia, ventricular tachycardia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac arrhythmia, SBRT, Stereotactic arrhythmia radioablation, Ventricular

tachycardia

Outcome measures

Primary outcome

Acceptable acute toxicity defined by CTCAE v5.0. The incidence of serious adverse events (SAEs, defined as >= grade 3) should be <33,33% within 90 days of treatment.

Secondary outcome

To demonstrate the efficacy of STAR as defined by the reduction in VT burden (number of ICD interventions and/or ATP, changes in antiarrhythmic medication), and improvement in quality of life (PROM questionnaires). The reduction in VT burden should be >= 50% after treatment compared to the 6 month period prior to STAR. To record (potential) late treatment related toxicity after STAR.

Study description

Background summary

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.This study will implement this treatment at UMC Utrecht under controlled conditions. The current study will also contribute to the STOPSTORM data registry, where granular data from over 200 patients will be aggregated to fine-tune the treatment.

Study objective

To deliver a single fraction stereotactic radiotherapy with acceptable toxicity and reduction in VT burden.

Study design

Prospective feasibility study.

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.

Study burden and risks

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 (esophagus, 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

medication and ablation therapy refractory ventricular arrhythmia

Exclusion criteria

extreme arrhythmia substrate: polymorphic VT/VF, >3 distinct clinical VT morphologies, >5 distinct induced VT morphologies during testing

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-11-2021
Enrollment:	11
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2021

Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-06-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24469
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76535.041.21
OMON	NL-OMON24469

Study results

Date completed: 01-10-2024

Summary results
Trial ended prematurely