Stereotactic Arrhythmia Radiotherapy in the Netherlands no. 1

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To evaluate the efficacy and safety of stereotactic arrhythmia radiotherapy in patients with therapy refractory ventricular tachycardia.

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

Summary

ID

NL-OMON48498

Source
ToetsingOnline

Brief title
STARNL-1 trial

Condition

- Cardiac arrhythmias

Synonym
heart rhythm disorder, ventricular arrhythmia, Ventricular tachycardia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Non-invasive cardiac ablation, Non-invasive cardiac mapping, Stereotactic

radiotherapy, Ventricular tachycardia

Outcome measures

Primary outcome

The main efficacy measure is a reduction in the number of treated VT episodes by *50% at one year after treatment compared to the year before treatment. The main safety measure for adverse cardiac effects is a >25% relative decrease in left ventricular ejection fraction measured by echocardiography at one year after treatment as compared to baseline and for adverse pulmonary effects a >25% relative decrease in forced expiratory volume in 1 second (FEV1) or diffusing capacity (DLCO) measured by pulmonary functions tests at one year after treatment as compared to baseline.

Secondary outcome

The secondary outcome measure is a *50% reduction in daily dose class 1 and 3 anti-arrhythmic drugs at one year after treatment as compared to baseline.

Study description

Background summary

Ventricular tachycardia (VT) is a malignant cardiac arrhythmia subjecting our patients to a high risk of sudden death, increased morbidity and reduced quality of life. Recent advances in cardiac electrophysiology and radiotherapy have enabled the use of non-invasive 3-dimensional cardiac mapping of these arrhythmias and the subsequent delivery of precise stereotactic radiotherapy to treat ventricular tachycardia.

Study objective

To evaluate the efficacy and safety of stereotactic arrhythmia radiotherapy in patients with therapy refractory ventricular tachycardia.

Study design

This will be a pre-post intervention study, single arm, phase 2, using non-invasive 3-dimensional cardiac mapping of ventricular tachycardia and the subsequent delivery of precise stereotactic radiotherapy to treat ventricular tachycardia designed to define efficacy and safety of this treatment in our patient population.

Intervention

The pro-arrhythmic cardiac region is identified by combining anatomical imaging with non-invasive body surface potential mapping during VT induction with non-invasive programmed stimulation. Radiotherapy simulation, planning and treatment is subsequently performed with the use of standard techniques. Patients are treated with a single radiotherapy fraction of 25 Gy at the determined pro-arrhythmic cardiac region.

Study burden and risks

Our study population will consist of critically ill and mostly older patients with a high disease burden, both somatically and psychologically. With non-invasive stereotactic radio-ablation therapy spectacular results have been reported with a decrease of over 90% in the occurrence of VT in therapy refractory patients. The impact of these results on disease burden and quality of life can be enormous. The promising results are accompanied by a simultaneously promising safety profile at 6 months and one year follow-up respectively. Late adverse cardiac effects after radiotherapy in the context of cancer treatment have been described. These effects will often be treatable if occurring. Furthermore, patients who will be eligible for this study have a significant decreased long-term survival.

The work-up for stereotactic radio-ablation therapy is extensive. If no recent image studies are available they will be repeated. Also, blood tests, an echocardiography and lung function tests will be performed. An electrophysiology study will be performed using body surface potential mapping to determine the starting point of the arrhythmia VT.

The treatment itself takes 15-20 minutes and is completely non-invasive and painless. After treatment with radiotherapy, patients will be observed for 24 hours at the cardiology department. Because this study involves a relative new treatment, patients will be closely monitored. Patients will have two additional outpatient clinic visits in comparison to patients undergoing conventional catheter ablation therapy. Furthermore, follow-up includes more blood tests, two times an echocardiography and two lung function tests to assess for potential adverse events.
We think these potential benefits outweigh the possible adverse effects in this

critical-ill patient population with no other therapeutic options. Furthermore, we think they justify the additional outpatient clinic visits and additional examinations.

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

- Age >18 years
- Implanted ICD
- World Health Organization (WHO) / Eastern Cooperative Oncology Group (ECOG) performance status grade 0-3 in the past 3 months (from fully active to capable of limited self-
care)
- At least 3 episodes of treated VT within the last 3 months

- Recurrence of VT after
o Failed or intolerance to at least one class 1 or class 3
anti-arrhythmic drug
AND
o At least one catheter ablation procedure OR considered to be
unsuitable for a catheter
ablation procedure (e.g. no sufficient vascular access,
considered unfit to undergo
prolonged general anesthesia, comorbid conditions resulting in
unacceptable peri-
procedural risks)
- Able and willing to undergo all necessary evaluations, treatment and
follow-up for the study and
of follow-up thereafter
- Informed consent

Exclusion criteria

- Pregnancy
- History of radiation treatment in the thorax or upper abdominal region
- Interstitial pulmonary disease
- Renal insufficiency with a glomerular filtration rate <30ml/min
- Refusal or inability to provide informed consent or to undergo all necessary
evaluations,
treatment and follow-up for the study

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	27-12-2019
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 22142
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68191.018.19
OMON	NL-OMON22142