StereoTactic Arrhythmia Radiotherapy in the NetherLands no. 1

No registrations found.

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

Summary

ID

NL-OMON22142

Source
NTR

Brief title
STARNL-1 trial

Health condition

Ventricular tachycardia

Sponsors and support

Primary sponsor: Amsterdam University Medical Centers
Source(s) of monetary or material Support: Government funding (university)

Intervention

Outcome measures

Primary outcome

The main efficacy measure is a reduction in the number of ICD treated VT episodes by ≥50% at one year after treatment compared to the year before treatment.

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. This study is designed to evaluate the efficacy and safety of stereotactic arrhythmia radiotherapy in patients with ventricular tachycardia.

Study objective

We hypothesize that stereotactic radiotherapy for the treatment of the cardiac arrhythmia ventricular tachycardia is effective and safe in therapy refractory patients

Study design

Outcomes will be assessed at 1, 3, 6 and 12 months after treatment

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.

Contacts

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Scientific
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Eligibility criteria

Inclusion criteria

1 Age >18 years

2 Implanted ICD

3 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, see below for full explanation)

4 At least 3 episodes of treated VT within the last 3 months

5 Recurrence of VT after
-Failed or intolerant to least one class 1 or class 3 anti-arrhythmic drug
AND
-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)

6 Able and willing to undergo all necessary evaluations, treatment and follow-up for the study and of follow-up thereafter

7 Informed consent

Exclusion criteria

1 Pregnancy

2 History of radiation treatment in the thorax or upper abdominal region

3 Interstitial pulmonary disease

4 Renal insufficiency with a glomerular filtration rate <30ml/min

5 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:	Recruiting
Start date (anticipated):	01-04-2019
Enrollment:	6
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48498
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7510
CCMO	NL68191.018.19
OMON	NL-OMON48498

Study results