Stereotactic Arrhythmia Radiotherapy in the Netherlands no. 2

Published: 13-07-2022
Last updated: 11-07-2024

To confirm our STARNL-1 pilot efficacy and safety data in a larger cohort and obtain insights in the mechanism of action by evaluating electro-anatomical alterations of stereotactic arrhythmia radiotherapy in patients with therapy refractory...

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

Summary

ID

NL-OMON51339

Source
ToetsingOnline

Brief title
STARNL-2 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: Hartstichting

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 is defined by a <=20% rate of treatment related serious adverse events.

Secondary outcome

Secondary efficacy measures include reduction of VT episodes by >=70%, changes in daily dose of anti-arrhythmic drugs and changes in quality of life comparing baseline to end of follow-up. Secondary safety measures include changes in cardiac and pulmonary function.

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. Unfortunately, failure of treatment is common and VT recurrences remain an important concern. In these patients, stereotactic arrhythmia radiotherapy appears to be an effective and safe treatment. The working mechanism however remains unknown and should be elucidated.

Study objective

To confirm our STARNL-1 pilot efficacy and safety data in a larger cohort and obtain insights in the mechanism of action by evaluating electro-anatomical alterations of stereotactic arrhythmia radiotherapy in patients with therapy

refractory ventricular tachycardia.

Study design

Pre-post intervention study, single arm, phase 2.

Intervention

Patients are treated with a single radiotherapy fraction of 25 Gy at the determined pro-arrhythmic cardiac region. The pro-arrhythmic cardiac region is determined by combining electro-anatomical information. Treatment is subsequently performed with the use of standard radiotherapy techniques as previously described.

Study burden and risks

At baseline, patients will undergo extensive evaluations to 1. determine the pro-arrhythmic region for treatment and 2. to gain baseline functional and electro-anatomical information. After radiotherapy simulation and planning, the radiotherapy treatment will be scheduled as a hospital admission. ICD interrogations, quality of life questionnaires, laboratory tests and assessment of adverse events will be performed at 1 week and 1, 3, 6, 9 and 12 months after treatment. Patients will undergo repeated electro-anatomical imaging and pulmonary function tests at 3 and 12 months.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

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 intolerant to 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

Exclusion criteria

- Pregnancy
- History of radiation treatment in the thorax or upper abdominal region
- Interstitial pulmonary disease

Study design

Design

Study phase: 2

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	13-07-2022
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCTnummervolgt.
CCMO	NL80617.018.22