# StereoTactic Arrhythmia Radiotherapy in the NetherLands no. 1

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22142

**Bron**
NTR

**Verkorte titel**
STARNL-1 trial

**Aandoening**

Ventricular tachycardia

### Ondersteuning

**Primaire sponsor:** Amsterdam University Medical Centers
**Overige ondersteuning:** Government funding (university)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

Amsterdam UMC, location AMC
P.G. Postema

020 566 9111

## Wetenschappelijk

Amsterdam UMC, location AMC
P.G. Postema

020 566 9111

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-04-2019 |
| Aantal proefpersonen: | 6 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 04-02-2019 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48498

Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten