Catheter ablation versus Amiodarone to pRevent Future ventricular tachycardia Episodes in patients with a defibrillator and a history of a myocardial infarction.

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Time to recurrence of sustained VT (longer that 30 seconds or with hemodynamic instability) or VF with or without documented ICD therapy (shock or ATP) for VT of VF will be longer in patients randomized to substrate based ablation than in patients...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21395

Bron
NTR

Verkorte titel
CARFE 2

Aandoening

Myocardial infarction, ICD Therapy, sustained VT

Ondersteuning

Primaire sponsor: Isala Klinieken, Locatie Weezenlanden, Department of Cardiology
Overige ondersteuning: Isala Klinieken, Maatschap Cardiologie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time to recurrence of sustained VT (longer that 30 seconds or with hemodynamic instability) or VF with or without documented ICD therapy (shock or ATP) for VT of VF during the follow-up period starting post ablation or after receiving amiodarone.

Toelichting onderzoek

Achtergrond van het onderzoek

The primary purpose of this randomized study is the assessment of recurrences of sustained VT and ICD therapy for VT or VF after appropriate ICD therapy (ATP or shock) in patients with a history of a myocardial infarction undergoing substrate based ablation compared to patients treated with amiodarone alone. Thus the primary purpose is reduction of time to next appropriate ICD therapy or sustained VT.

Doel van het onderzoek

Time to recurrence of sustained VT (longer that 30 seconds or with hemodynamic instability) or VF with or without documented ICD therapy (shock or ATP) for VT of VF will be longer in patients randomized to substrate based ablation than in patients randomised to amiodarone.

Onderzoeksopzet

Patients will be seen by the investigator at baseline, 2, 6, 12, 18, 24 months and at 6 month intervals (at the discretion of the investigator) until completion of the follow up.

Onderzoeksproduct en/of interventie

Catheter ablation or medical therapy with Amiodaron. Both interventions are already used in daily practice, but they have never been compared.

Amiodarone dosing: Starting dose:

1. Oral: 1 week 600mg per day, 1 week 400mg per day, afterwards 200mg per day;

2. Starting i.v.: 1200mg/24 hour loading dose and afterwards 200mg daily.

Contactpersonen

Publiek

Diagram B.V. Zwolle
Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997

Wetenschappelijk

Diagram B.V. Zwolle
Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Prior myocardial infarction, at least 3 months ago;

2. ICD implantation for any cause except for: Brugada syndrome, ARVC, HCM, LQTS, SQTS, cathecholaminergic polymorphic VT, other channelopathies;

3. ICD therapy (shock or ATP) for VT or VF without a reversible cause. Reversible causes (must be checked):

A. Acute myocardial ischemia in the following circumstances:

i. Acute coronary syndrome;

ii. Myocardial ischemia as documented by non-invasive myocardial ischemia testing what can be treated by revascularisation.

B. Whenever VT or VF occurs in the setting of antiarrhythmic medication intake (class I or III Vaughn-William) with increased QTc, the patient will not be a candidate for enrolment;

C. High fever (T>39 degrees Celsius) and signs of infection/sepsis at presentation will exclude patient from enrolment;

D. Lead dislocation on X-ray plus signs of mechanical VT induction will exclude patients from the study;

E. Other reversible causes as significant hypoxemia not caused by cardiac failure or known hyperthyroidism. Judgement whether this will be possible cause of VT/VF will be at discretion of the attending physician.

4. Optimal revascularization before ICD implantation performed;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years;

2. Use of amiodarone more than 7 days before randomization within the period of 3 months before randomization. If a patient used amiodarone in preceding 3 months, the plasma levels of amiodarone and desethylamiodarone will be determined. If both levels are > 1mg/L the patient will be excluded from the study;

3. Inability to use amiodarone due to past side effects;

4. Class I antiarrythmic drugs not stopped ≤ 5 times ½T prior to randomization;

5. Protruding LV thrombus or cardiac tumor on pre-ablation echocardiogram;

6. Acute myocardial infarction within the preceding 3 months;

7. Non-reversible Class IV NYHA heart failure;

8. Valvular heart disease or mechanical heart valve precluding access to the left ventricle;

9. Unstable coronary artery syndrome or active myocardial infarction;

10. Cardiac surgery within the past 2 months;

11. Mechanical mitral or tricuspid valve prothesis;

12. Serum creatinine > 220 mmol/L (2.5 mg/dL);

13. Thrombocytopenia or coagulopathy;

14. Contraindication to anticoagulation;

15. Stroke within past 30 days;

16. Pregnancy;

17. Acute illness or serious active systemic infection;

18. Other disease process likely to limit survival to less than 12 months;

19. Lack of availability for follow-up.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	116
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-03-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2674
NTR-old	NTR2802
Ander register	EudraCT / METC : 2011-001141-32 / 11.0333;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A