

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

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It is assumed that recurrence of appropriate ICD shocks is 30% in the Amiodarone group and 16% in the Ablation group.

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

Samenvatting

ID

NL-OMON22288

Bron

NTR

Verkorte titel

CARFE

Aandoening

Catheter ablation

ICD shock

VT / VF

defibrillation

MI

Ondersteuning

Primaire sponsor: Maatschap cardiologie Isala klinieken Zwolle

Overige ondersteuning: Maatschap cardiologie Isala klinieken Zwolle

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time to recurrence of documented ICD shock therapy for VT or VF during the follow-up period starting post ablation or after receiving amiodarone.

Toelichting onderzoek

Achtergrond van het onderzoek

The primary purpose of Single-center, prospective, randomized, open trial study is the assessment of recurrences of ICD therapy for VT or VF after appropriate ICD shock therapy 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 shock. It is assumed that recurrence of appropriate ICD shocks is 30% in the Amiodarone group and 16% in the Ablation group.

Doel van het onderzoek

It is assumed that recurrence of appropriate ICD shocks is 30% in the Amiodarone group and 16% in the Ablation group.

Onderzoeksopzet

Visits at: Baseline, 2, 6, 12, 18, 24 and 36 months.

Time to documented ICD shock therapy for VT or VF during the follow up period starting post ablation or after receiving Amiodarone.

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.

Contactpersonen

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Wetenschappelijk

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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, catecholaminergic polymorphic VT, other channelopathies;
3. ICD shock 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.

The contribution of electrolyte abnormalities to an episode of unstable VT is notoriously difficult to ascertain, especially if the abnormal electrolyte level is noted after cardiopulmonary resuscitation. In view of this fact, abnormal electrolyte levels will not be used in assessing eligibility for enrolment.

Although volume overload due to heart failure is a possible trigger for VT/VF, it can also be caused by an episode of VT/VF. Therefore, this will not be marked as a reversible cause. If, however, the patient is not successfully treated for the episode of volume overload, he can be excluded from the study. This decision will be at the discretion of the attending physician.

Patients with a cluster of VTs (electrical storm) who require urgent RF ablation are not suitable candidates for our study. Whether these patients require urgent intervention, will be left at the discretion of the investigator. These patients will be registered.

4. Optimal revascularization before ICD implantation performed;

5. Written informed consent.

Patients who meet the inclusion and exclusion criteria and sign the informed consent will be considered enrolled in the study. No patient will be enrolled without an informed consent document signed by the patient. Informed consent forms have to be in compliance with the latest Declaration of Helsinki.

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 antiarrhythmic drugs not stopped ;Â 5 times ``ÖT 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
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	238
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	11-11-2009
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	NL1987
NTR-old	NTR2104
Ander register	METC : 09.0111
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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