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

No registrations found.

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

Summary

ID

NL-OMON22288

Source
NTR

Brief title
CARFE

Health condition

Catheter ablation
ICD shock
VT / VF
defibrillation
MI

Sponsors and support

Primary sponsor: Maatschap cardiologie Isala klinieken Zwolle
Source(s) of monetary or material Support: Maatschap cardiologie Isala klinieken Zwolle

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Total number of ICD shocks during follow-up period;

2. Number of VT’s recorded by the ICD;

3. Quality of life (SF-36 score);

4. Number of hospital readmissions due to a cardiovascular indication;

5. Number of appropriate ICD therapies (including ATP);

6. Number of appropriate ICD shocks;

7. Number of inappropriate ICD therapies (including ATP);

8. Number of inappropriate ICD shocks;

9. Severe clinical events (death, syncope’s, electrical storm episodes (defined as > 3 sustained VT episodes within 24 hours) and cessation of amiodarone due to side-effects).

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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 shock for VT of 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.

Exclusion criteria

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 ¡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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2009
Enrollment:	238
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-11-2009
Application type:	First submission

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
NTR-new	NL1987
NTR-old	NTR2104
Other	METC : 09.0111
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

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