Ventricular Tachycardia Ablation vs. ENhanced Drug Therapy In Structural Heart Disease

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To compare aggressive antiarrhythmic drug therapy to catheter ablation (ablation) for ventricular tachycardia (VT) in patients who have suffered prior myocardial infarction.

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

Summary

ID

NL-OMON36099

Source
ToetsingOnline

Brief title
VANISH study

Condition

- Cardiac arrhythmias

Synonym
arrhythmia, ventricular arrhythmia, ventricular tachycardia

Research involving
Human

Sponsors and support

Primary sponsor: The Queen Elizabeth II Health Sciences Centre
Source(s) of monetary or material Support: Biosense Webster,Biosense Webster en St Jude Medical (beide biotechnologische industrie),Canadian Institutes of Health Research,St. Jude Medical

Intervention

Keyword: anti-arrhythmic drugs, catheter ablation, myocardial infarction, ventricular tachycardia

Outcome measures

Primary outcome

The primary endpoint will be a composite of death, appropriate ICD shock and VT storm. Shocks and storm during a 1 month post-randomization treatment period will be considered as secondary endpoints. Patients will be followed up for a minimum of 3 years.

Secondary outcome

Secondary endpoints will include the following: all cause mortality, appropriate ICD antitachycardia pacing anytime and after 1 month treatment period, appropriate ICD shocks anytime and after 1 month treatment period, VT storm anytime and after 1 month treatment period, documented sustained VT below detection rate of the ICD any time and after 1 month treatment period, inappropriate shocks anytime and after 1 month treatment period, number of ICD shocks, hospital admission for cardiac causes, procedural complications, amiodarone toxicity or adverse events, effects on ejection fraction, quality of life/anxiety and cost-effectiveness.

Study description

Background summary

The most appropriate management for patients with implantable defibrillators (ICDs) who experience recurrent ventricular arrhythmias is unknown. Standard first-line therapy usually involves either sotalol or amiodarone. When patients

experience recurrent therapy despite these drugs, however, some clinicians would advocate ablation as an alternative to more aggressive pharmacologic therapy, while others would change or increase drug therapy. There is no evidence to guide practice for this increasingly frequent clinical situation.

Study objective

To compare aggressive antiarrhythmic drug therapy to catheter ablation (ablation) for ventricular tachycardia (VT) in patients who have suffered prior myocardial infarction.

Study design

This trial will be a multicentre, parallel group, two arm, unblinded randomized clinical trial.

Intervention

Group 1- Aggressive Antiarrhythmic Drug therapy. Patients randomized to aggressive antiarrhythmic drug therapy will be treated with amiodarone or amiodarone plus mexiletine.

Group 2- Catheter Ablation. Patients randomized to ablation will be scheduled to undergo the procedure within 14 days, all induced VTs will be targeted for ablation and patients will remain on the previously ineffective drug therapy after the procedure.

Study burden and risks

Both catheter ablation and aggressive pharmacological management for recurrent ventricular tachycardia are common clinical approaches, and there is clinical equipoise between them. The only additional procedures required by the study are quality of life questionnaires, echocardiography, blood work and noninvasive testing. The risk of study participation, therefore, is no different from usual standard care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Prior myocardial infarction (pathological Q waves or imaging evidence of regional myocardial akinesis/thinning in the absence of a non-ischemic cause)73
2. An implantable defibrillator
3. One of the following VT events (within last 3 months):
A: *3 episodes of symptomatic VT treated with antitachycardia pacing (ATP),
B: *1 appropriate ICD shocks,
C: *3 VT episodes within 24 hr
D: sustained VT below detection rate of the ICD documented by ECG/cardiac monitor
4. *Failed* first-line antiarrhythmic drug therapy (Class 1 or 3) as defined by one of:
A: Appropriate ICD therapy or sustained VT occurred while the patient was taking amiodarone (patient on a stable dose for * 2 weeks)
B: Appropriate ICD therapy or sustained VT occurred on another antiarrhythmic drug (patient on a stable dose for * 2 weeks)

Exclusion criteria

1. Are unable or unwilling to provide informed consent.
2. Have an acute coronary syndrome (acute thrombus diagnosed by coronary angiography, or dynamic ST segment changes demonstrated on ECG) or another reversible cause of VT (e.g. electrolyte abnormalities, drug-induced arrhythmia)

3. Are known to be ineligible to take amiodarone, e.g. active hepatitis, current hyperthyroidism, pulmonary fibrosis, known allergy.
4. Are ineligible for ablation (known to have protruding left ventricular thrombus, or have implanted mechanical aortic and mitral valves)
5. Are in renal failure (Creatinine clearance <15 ml/min)
6. Have current NYHA Functional class IV heart failure or CCS Functional class IV angina
7. Had recent ST elevation myocardial infarction (< 1 month)
8. Had recent coronary bypass surgery (< 3 months) or percutaneous coronary intervention (<1 month)
9. Are pregnant
10. Have had prior ablation for ventricular tachycardia
11. Have a systemic illness likely to limit survival to < 1 year.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	09-08-2011
Application type:	First submission

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-11-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NCT#00905853
CCMO	NL36631.058.11