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The aim of the study is to demonstrate a survival benefit of ICD in patients with high-risk characteristics after primary angioplasty for acute MI.

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

Samenvatting

Bron

NTR

Verkorte titel

DAPA

Aandoening

primary angioplasty for acute MI within 30-60 days with at least one of the following criteria:
1) TIMI flow after PCI less than 3;
2) left ventricular ejection (LVEF) lower than 30% as measured within 4 days after hospital admission.

Ondersteuning

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Overige ondersteuning :	Medtronic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of the study is all-cause mortality.

Toelichting onderzoek

Achtergrond van het onderzoek

Background – Sudden cardiac death is a major cause of death after acute myocardial infarction (AMI). Several studies have shown that an Implantable Cardioverter Defibrillator (ICD) is superior to antiarrhythmic drug treatment in patients who survived an arrhythmic cardiac arrest or an episode of life-threatening ventricular tachycardia. Furthermore, ICD as primary prevention therapy has been accepted in patients with coronary artery disease, decreased systolic left ventricular (LV) function and inducible sustained ventricular tachyarrhythmias. Recently, a prospective randomized study showed that defibrillator therapy was beneficial when added to optimal drug treatment in patients with reduced LV function who survived a myocardial infarction (MI). However, it is not known which patients who have mechanical reperfusion as therapy for AMI could have benefit of prophylactic ICD therapy to reduce sudden cardiac death. Furthermore, since LV function improves in the months after MI, particularly after primary PCI, prophylactic ICD implantation based solely on LV function in the post acute phase of MI is probably not a good criterium for ICD implantation within 30 days.
Design – Prospective randomized study to compare ICD plus conventional medical therapy versus conventional medical therapy alone in patients who survived an AMI treated with primary angioplasty. All patients will be treated with optimized drug-therapy including angiotensin-converting enzyme inhibitors, â-blockers, aspirin and lipid-lowering drugs where appropriate. Additional revascularisation procedures are to the discretion of the investigators. After written informed consent has been obtained patients are randomized in a 1:1 ratio to receive either an ICD or conventional medical therapy alone.
A single-chamber ICD will be implanted, preferably, in the left subclavian area and will be tested in the catheterization laboratory under general anesthesia.
Aims – The aim of the study is to demonstrate a survival benefit of ICD in patients with high-risk characteristics after primary angioplasty for acute MI.
Patients – Inclusionafter primary angioplasty for acute MI within 30-60 days with at least one of the following criteria: 1) TIMI flow after PCI less than 3; 2) left ventricular ejection (LVEF) lower than 30% as measured within 4 days after hospital admission. After 18 months LVEF

will be measured and all patients in the conventional medical therapy group with LVEF < 30% will be eligible for ICD implantation. Follow-up will be up to 3 years after randomization. Exclusion criteria include patients who are unwilling or unable to sign the consent form for participation and those in who follow-up cannot be obtained (e.g. foreign patients). Also patients in cardiogenic shock will be excluded.
Sample size calculations – Survival estimations are based on data from the GIPS study, a recently reported study from Zwolle assessing Glucose Insulin Potassium in 940 patients with primary angioplasty. One year mortality was in this trial 7.3%. Based on the above mentioned criteria, a total of 169 patients would have been eligible for inclusion (18%). One-year mortality in this group was 22%, with early mortality 10%. It is assumed that ICD therapy will cause a decrease of 1/3 of the 'late'mortality. After 3 years, 'late'mortality will be 32% in the controls, compared to 21.3% in the patients with ICD. A total of 538 patients would be required to demonstrate a significant difference with power 0.8 and alpha 0.05. Because cross-over in the control group can dilute the effect, the sample size will be increased with 30%, resulting in a final sample size of 700 patients, with 350 patients in each group.
End points – The primary endpoint of the study is all-cause mortality. Secondary endpoints are the incidence of sudden cardiac death and sustained ventricular tachycardia (VT). Sudden cardiac death is defined as occurring within 1 hour of the onset of symptoms or, if death is not witnessed, during sleep or within 24 hours of last occasion on which the patient was seen in a healthy state.

Doel van het onderzoek

The aim of the study is to demonstrate a survival benefit of ICD in patients with high-risk characteristics after primary angioplasty for acute MI.

Onderzoeksproduct en/of interventie

ICD implantation.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

ST-elevation myocardial infarction treated with primary PCI within 30 days and 60 days before randomisation2.At least one of the following criteria:

1. TIMI flow after primary PCI less than 3 in the infarct related vessel;

2. Left ventricular ejection lower than 30% as measured within 4 days after admission.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Class I indication for ICD implantation;

2. Documented previous myocardial infarction with LVEF < 30%;

3. Age < 18 years;

4. Heart failure with New York Heart Association functional class IV;

5. Inotropic medication within 2 weeks before randomisation;

6. Mechanical tricuspid valve;

7. Serious comorbidity such as cancer, with a high likelihood of death during the trial;

8. Advanced cerebrovascular disease;

9. Unwilling or unable to sign the consent form for participation;

10. Females of childbearing age not using medically prescribed contraceptives.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status :	Werving gestart
(Verwachte) startdatum :	03-03-2004
Aantal proefpersonen :	700
Type :	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum :	02-08-2005
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	NL74
NTR-old	NTR105
Ander register	: N/A
ISRCTN	ISRCTN42195152

Resultaten

Samenvatting resultaten

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