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Defibrillator After Primary Angioplasty randomised trial

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2021	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Defibrillator After Primary Angioplasty randomised trial

Acronym

DAPA

Study objectives
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 anti-arrhythmic 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 randomised 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 Percutaneous Coronary Intervention (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.

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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group, multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular

Interventions
Patients will be randomised in a 1:1 ratio to receive either ICD implantation with conventional medical therapy versus conventional medical therapy alone. All patients will be treated with optimised drug-therapy including angiotensin-converting enzyme inhibitors, alpha-blockers, aspirin and lipid-lowering drugs where appropriate. Additional revascularisation procedures are to the discretion of the investigators.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary endpoint of the study is all-cause mortality.

Key secondary outcome(s))
Secondary endpoints are the incidence of sudden cardiac death and sustained Ventricular Tachycardia (VT). Sudden cardiac death is defined as occurring within one 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.

Completion date
31/03/2008

Eligibility

Key inclusion criteria
1. ST-elevation myocardial infarction treated with primary PCI within 30 days and 60 days before randomisation
2. At least one of the following criteria:
a. Thrombolysis In Myocardial Infarction (TIMI) flow after primary PCI less than three in the infarct related vessel
b. Left ventricular ejection lower than 30% as measured within four days after admission

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
266

Key exclusion criteria
1. Class I indication for ICD implantation
2. Documented previous myocardial infarction with Left Ventricular Ejection Fraction (LVEF) less than 30%
3. Age less than 18 years
4. Heart failure with New York Heart Association functional class IV
5. Inotropic medication within two 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

Date of first enrolment
03/03/2004

Date of final enrolment
31/03/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Diagram B.V.
Zwolle
Netherlands
8011 NB

Sponsor information

Organisation
Individual Sponsor (Netherlands)

Funder(s)

Funder type
Industry

Funder Name
Medtronic B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results			26/03/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes