

Defibrillator After Primary Angioplasty randomised trial

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| Submission date 12/09/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/09/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 26/03/2021 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.diagram-zwolle.nl>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

03/03/2004

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

700

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)

Sponsor details

Dr A R Ramdat Misier

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Sponsor type

Other

Funder(s)

Funder type

Industry

Funder Name

Medtronic B.V. (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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 |