

Next-day discharge after primary percutaneous Coronary Intervention PCI

Submission date 26/11/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/12/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/03/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

According to the present guidelines, low risk patients who undergo primary percutaneous coronary intervention (PPCI) for acute myocardial infarction (AMI), could be discharged safely 3 days after admission. In this study, we investigated the safety and feasibility of next-day hospital discharge in patients treated with PPCI.

Who can participate?

Low risk PPCI patients.

What does the study involve?

Patients discharged within 36 hours after admission.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Isala Hospital, Zwolle, Netherlands

When is the study starting and how long is it expected to run for?

July 2008 to July 2013

Who is funding the study?

Isala Hospital, Zwolle, Netherlands

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

Diagr. 9196

Study information

Scientific Title

Safety and Feasibility of Next-Day Discharge after Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction

Acronym

Short Stay

Study objectives

Very early discharge (e.g. within one day) in ST segment elevation myocardial infarction (STEMI) patients undergoing uncomplicated primary PCI, and with low risk based on a validated risk score, is safe and feasible

Ethics approval required

Old ethics approval format

Ethics approval(s)

Under the Dutch Law for medical scientific research in humans (Wet Medisch-wetenschappelijk Onderzoek met mensen WMO)no ethics approval was needed. There was no submission to an ethics committee.

Study design

Prospective single centre safety and feasibility study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction

Interventions

Patients were discharged within 36 hours after admission and controlled by specialized nurses in the outpatient clinic at the third and fourth day after PPCI.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Occurrence of major adverse cardiac event, defined as death, re-myocardial infarction, urgent target vessel revascularisation and myocardial infarction related (potentially)
2. Life threatening arrhythmias, as defined as ventricular tachycardia and complete atrioventricular block

Key secondary outcome(s)

1. Re-admission rates
2. Number of visits to emergency ward of any cause at 30 day follow-up and 1 year follow-up

Completion date

01/07/2013

Eligibility

Key inclusion criteria

1. Patients with ST-elevated myocardial infarction, successfully treated with PPCI
2. Procedural was defined as an uncomplicated procedure resulting in restoration of flow with a sufficient myocardial blush in the area of the infarction related vessel
3. Procedure was performed via the femoral artery (Seldinger technique)
4. Patient with a Zwolle risk Score ≤ 3
5. Patient that is, after discharge, able to reach the hospital within 30 minutes
6. Patient that gives written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with untreated significant coronary artery stenosis
2. Patients <18 years old, or unable to co-operate with the study
3. Patients living >30 km from the PCI center

Date of first enrolment

01/07/2008

Date of final enrolment

01/07/2013

Locations**Countries of recruitment**

Netherlands

Study participating centre**Isala**

Dr. v. Heesweg 2

Zwolle

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Sponsor information**Organisation**

Maatschap Cardiologie, Isala Hospital

ROR

<https://ror.org/046a2wj10>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Maatschap cardiologie Isala Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request