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Next-day discharge after primary percutaneous Coronary Intervention PCI

Submission date 26/11/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/12/2014	**Overall study status** Completed	
Last Edited 05/03/2019	**Condition category** Circulatory System	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

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

Overall study start date
01/07/2008

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

Age group
Adult

Sex
Both

Target number of participants
250

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
Netherlands
8025 AB

Sponsor information

Organisation
Maatschap Cardiologie, Isala Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maatschap cardiologie Isala Hospital

Results and Publications

Publication and dissemination plan
We are planning to submit a report of the results for the first 250 patients in the upcoming 2 months. The results will consist of the detailed survival and adverse events in the first 30 days following inclusion, and mortality data of the first year after inclusion.

2017 results in Chapter 3 of thesis https://cris.maastrichtuniversity.nl/ws/files/12653600/c5627.pdf

Intention to publish date

31/03/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request