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A randomised trial comparing same-day discharge with overnight hospital stay after elective percutaneous coronary intervention (PCI): the Elective Percutaneous coronary intervention in Outpatient Study

Submission date 24/10/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2005	**Overall study status** Completed	
Last Edited 29/07/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

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

Acronym
EPOS

Study objectives
The Elective PCI in Outpatient Study (EPOS) is designed to evaluate the safety and feasibility of discharge the same day as PCI, by testing the hypothesis that patients requiring extended observation can be selected effectively and that same-day discharge does not increase the complication rate as compared to overnight hospital stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Angina pectoris

Interventions
After percutaneous coronary intervention, patients are observed for 4 hours.
1. Patients randomized to same-day discharge are ambulated after this period and discharged.
2. Patients randomized to overnight stay are discharged the following day. Indications for extended hospital stay are based on pre-defined clinical and angiographic criteria.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary endpoint of the study is the composite of major adverse cardiac events and severe complications of the arterial puncture with the need of blood transfusion or repeat compression, from randomization until 24 hours after PCI.

Secondary outcome measures
1. Indication for extended observation
2. The occurrence of major adverse cardiac events and puncture site complications from randomization until 30 days after PCI
3. Quality of life scores before and after PCI
4. Actual costs related to PCI, aftercare and 30 days follow-up

Overall study start date
01/07/2000

Completion date
21/03/2003

Eligibility

Key inclusion criteria
Patients scheduled to undergo elective percutaneous coronary intervention in the Academic Medical Centre in Amsterdam who remain at home prior to the procedure

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
800

Key exclusion criteria
1. Scheduled use of guiding catheters larger than 6 French (F) in diameter
2. Elective use of glycoprotein 2b/3a receptor blockers
3. Long-term systemic anti-coagulation
4. Residence of more than 60 minutes drive from an intervention center
5. No adult care person available at home for first 24 hours after PCI
6. Diagnostic coronary artery catheterization with possible ad hoc PCI

Date of first enrolment
01/07/2000

Date of final enrolment
21/03/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center, Amsterdam (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Dutch Health Care Insurance Board (CVZ, independent government organisation)

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?
Results article	results	01/05/2007		Yes	No