

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
Registration date 25/10/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/07/2014	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

Funder(s)

Funder type

Other

Funder Name

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

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?
Results article	results	01/05/2007		Yes	No