A Randomised Trial Comparing Same-Day Discharge with Overnight Hospital Stay after Elective Percutaneous Coronary Intervention: the Elective Percutaneous Coronary Intervention in Outpatient Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24859

Source
NTR

Brief title
EPOS

Health condition

Stable angina.

Sponsors and support

Primary sponsor: Academic Medical Centre-University of Amsterdam

Meibergdreef 15
1105 AZ Amsterdam
Netherlands
tel: 31 20 5669111
Source(s) of monetary or material Support: Dutch Health Care Insurance Board (CVZ,

independent governement organisation)

P.O. box 320
1110 AH Diemen
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www.cvz.nl

Intervention

Outcome measures

Primary outcome

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

Secondary endpoints are the indication for extended observation, the occurrence of major adverse cardiac events and puncture site complications from randomization until 30 days after PCI, quality of life scores before and after PCI, actual costs related to PCI, aftercare and 30 days follow-up.

Study description

Background summary

N/A

Study objective

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.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

All patients scheduled to undergo elective percutaneous coronary intervention in the Academic Medical Centre in Amsterdam who remain at home prior to the procedure.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2000
Enrollment:	800
Type:	Actual

Ethics review

Positive opinion

Date:	30-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL134
NTR-old	NTR168
Other	: N/A
ISRCTN	ISRCTN75891755

Study results

Summary results
Circulation. 2007 May 1;115(17):2299-306. Epub 2007 Apr 9.