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

Gepubliceerd: 30-08-2005 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24859

Bron
NTR

Verkorte titel
EPOS

Aandoening

Stable angina.

Ondersteuning

Primaire sponsor: Academic Medical Centre-University of Amsterdam

Meibergdreef 15
1105 AZ Amsterdam

Netherlands
tel: 31 20 5669111
Overige ondersteuning: Dutch Health Care Insurance Board (CVZ, independent governement organisation)

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2000
Aantal proefpersonen:	800
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

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