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Cypher drug-Eluting stent: a Zwolle Acute myocardial infarction Randomised trial

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2021	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.diagram-zwolle.nl

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
Cypher drug-Eluting stent: a Zwolle Acute myocardial infarction Randomised trial

Acronym
CEZAR

Study objectives
The study is designed to demonstrate superiority of Cypher stent based on the assumption that at follow-up angiography the late loss is at least 0.15 mm smaller than the mean late loss when the Taxus stent is used.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group, single centre 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
Acute myocardial infarction

Interventions
Percutaneous Coronary Intervention using either the Bx VELOCITYTM stent coated with rapamycin (Cypher) or the TaxusTM stent coated with Paclitaxel.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Major adverse cardiac clinical events (death, re-infarction, target vessel revascularisation) at one, nine and 12 months after treatment.

Secondary outcome measures
Late lumen loss at nine months follow-up by quantitative coronary angiography

Overall study start date
01/06/2004

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Patients with acute myocardial infarction, presenting within six hours after symptom-onset, or those presenting between six and 24 hours if persisting chest pain associated with clinical evidence of on-going ischaemia occurs
2. Culprit lesion in a native coronary artery, suitable for stenting
3. Lesion length of less than 30 mm, located in a vessel of more than 2.5 mm
4. Able to deliver the stent to target lesion (absence of diffuse disease or excessive proximal vessel tortuosity)
5. Absence of no-reflow or extensive thrombus throughout vessel

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
352

Key exclusion criteria
1. Women of child-bearing potential
2. Severe hepatic or renal disease
3. Previous participation in the study
4. Life expectancy of less than one year
5. Factors making follow-up difficult
6. Acute myocardial infarction pre-treated with thrombolysis
7. Unprotected left main disease or single remaining vessel
8. Target lesion in a bifurcation with a large side-branch
9. Known sensitivity to aspirin or coumarin
10. Unable to provide informed consent

Date of first enrolment

01/06/2004

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Diagram B.V. Zwolle
Zwolle
Netherlands
8011 NB

Sponsor information

Organisation
Isala klinieken (The Netherlands)

Sponsor details
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Department of Cardiology
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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