

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

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/08/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute myocardial infarction

Interventions

Percutaneous Coronary Intervention using either the Bx VELOCITY™ stent coated with rapamycin (Cypher) or the Taxus™ stent coated with Paclitaxel.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

<https://ror.org/046a2wj10>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes