Xience V stent vs. Cypher stent in all-comer patients: A randomized trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26637

Source
NTR

Brief title
APPENDIX-AMI

Health condition

Patients with coronary artery disease undergoing percutaneous coronary intervention

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden,
Cardiologie poli 67
Henri Dunantweg 2
8934 AD Leeuwarden
The Netherlands
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

Clinical MACE at 1 year (cardiac mortality, non-fatal myocardial infarction, TVR).

Secondary outcome

1. (Sub)-acute stent thrombosis (SAT) at 30 days and late stent thrombosis (LST) at 1, 2 and 3 year;

2. Clinical MACE at 30 days and 2 and 3 years (cardiac death, non-fatal MI, TVR);

3. All cause mortality at 1, 2 and 3 year.

Study description

Background summary

This is a prospective randomized study designed to compare the effectiveness and safety, defined as clinical MACE at 12 months follow up, of the Xience V stent with the Cypher stent in all patients treated with PCI in the MCL. In order to study the long-term safety of the both DES, follow-up is planned for 3 years.

Study objective

To assess the effectiveness of the Xience stent compared to the CYPHER stent in the PCI treatment of all patients in the MCL during 2007- 2008. This study runs parallel with the XAMI study.

Study design

18 months enrolment, and 36 month follow up.

Intervention

PCI with stent placement.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient is willing to sign the informed consent;

2. Patient is willing to perform all follow-up examinations as required by the protocol;

3. Patient eligible for coronary revascularization intervention by PCI and stenting;

4. Patient is located in a geographic area that will enable contact by the study site for follow-up.

Exclusion criteria

1. Patients who are minor, intravenous drug abusers, alcohol abuser, prisoners or unable to give informed consent;

2. Patients who are allergic to everolimus or sirolimus;

3. Patients with known intolerance or contra-indications to treatment with acetylsalicylic acid or clopidogrel;

4. Patients in whom the cardiologist judges that stent implantation is not possible, realistic or justified.

Study design

Design

Study type: Interventional

Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2007
Enrollment:	2000
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-12-2011
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	NL3022
NTR-old	NTR3170
Other	METC : RTPO486a
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A