XienceV stent vs Cypher stent in primary PCI for acute myocardial infarction.

No registrations found.

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

Summary

ID

NL-OMON27542

Source
Nationaal Trial Register

Brief title
XAMI

Health condition

1. Acute myocardial infarction;

2. drug-eluting stent.

Sponsors and support

Primary sponsor: Dr. S.H. Hofma
Medisch centrum Leeuwarden
cardiologie poli 67
Henri Dunantweg 2
8934 AD Leeuwarden
The Netherlands
shhofma@hetnet.nl
+31-58 2867766
Source(s) of monetary or material Support: Abbot (non restricted grand);
Cordis NL (non restricted grand).

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 year (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 multi-center study designed to assess clinical performance of the Xience stent in AMI patients compaired to the CYPHER.
The patient will undergo a clinical examination to assess their clinival status and the occurrence of adevrse clinical events before and after the procedure and follow-up at 30 days, 1, 2 and 3 years after the procedure.

Study objective

Essess the effectiveness of the Xience stent compared to the CYPHHER stent in the treatment of acute myocardial infarction patients.

Study design

18 month enrolment and 36 month follow-up.

Intervention

PCI with stent placement.

Contacts

Public
Diagram B.V. Zwolle
Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997
Scientific
Diagram B.V. Zwolle
Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997

Eligibility criteria

Inclusion criteria

1. Patients with acute ST elevated myocardial infarction;

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

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

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

Exclusion criteria

1. Chronical total occlusion as target lesion intervention;

2. stent thrombosis or previous stent at target lesion;

3. drug,-alcohol abusers or prisoners;

4. allergic to everolimus or sirolimus;

5. intolerance or contra-indicated to treatment with acetylsalicylic acid or clopidogrel;

6. over 80 years old;

7. stent implantation not possible, judged by cardiologist;

8. intubated patients;

9. life expectancy < 1 year;

10. stent size >3.5 mm required to treat lesion.

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:	800
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-11-2007
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	NL1090
NTR-old	NTR1123
Other	XAMI : ABR NL17690.0099.07 Diagr. 9056
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A