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STRESSED study: direct Stenting To reduce REStenosis in Stent Era with Drug elution

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/04/2015	Circulatory System	

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

NTR111

Study information

Scientific Title
STRESSED study: direct Stenting To reduce REStenosis in Stent Era with Drug elution

Acronym
STRESSED

Study objectives
To investigate whether a strategy of direct stenting without pre-dilatation is associated with a reduced incidence of restenosis at nine month follow-up angiography, compared to conventional stenting with pre-dilatation or compared to a strategy of provisional stenting.

Please note that as of 24/06/2008 more details on the sources of funding have been added to this record (i.e., funding now confirmed). This can be seen below in the sources of funding section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the METC Isala klinieken Zwolle, 28/06/2005, ref: 04.1178p

Study design
Randomised active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Angina pectoris, myocardial infarction

Interventions
Pecutaneous coronary intervention:
Randomisation to drug eluted stenting (DES) without (group Direct), with (group Conventional) balloon predilatation or provisional stenting (group Provisional).

600 patients with stable or unstable angina, who are candidate for a percutaneous transluminal coronary angioplasty (PTCA), will be randomised to direct stenting, provisional stenting or pre-delatation. After nine months a follow up angiogram will be made. After 24 month a follow-up will be done.

Intervention Type
Procedure/Surgery

Primary outcome measure
Mean minimal lumen diameter at follow-up angiography.

Secondary outcome measures
1. Clinical procedural success defined as angiographic success without major adverse cardiac events (MACE): death, myocardial infarction, or myocardial revascularisation by repeat angioplasty or coronary bypass surgery
2. Rate of major adverse clinical events during the nine and 24-month follow-up period

Overall study start date
01/09/2005

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Men and women less than 85 years of age
2. Stable or unstable angina pectoris or a recent (less than 30 days) myocardial infarction with objective evidence of myocardial ischaemia
3. Lesion with more than 50% and less than 100% diameter stenosis according to the estimate of the investigator
4. Single American College of Cardiology/American Heart Association (ACC/AHA) task force classification type A, B1 or B2 non-calcified target lesion
5. No contraindication to inhibition of platelet function with aspirin and ticlopidine or clopidogrel

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Acute ST elevation myocardial infarction
2. Unstable angina pectoris, classified as Braunwald category IIIB or C

3. Bifurcation lesions situated with a side branch more than 20 mm in diameter
4. Left main coronary artery lesions
5. Ostial lesions
6. Left ventricular ejection fraction of less than 30%
7. Contraindication for follow-up angiography (severe peripheral vessel disease, creatine-clearance less than 30 ml/min)

Date of first enrolment
01/09/2005

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Netherlands

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

Sponsor information

Organisation
Isala Clinics (Isala klinieken) (The Netherlands)

Sponsor details
Locatie Weezenlanden
Department of Cardiology
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Sponsor type
Hospital/treatment centre

Website
http://www.isala.nl/

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Industry

Funder Name
Diagram B.V. (The Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No