

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised active-controlled parallel-group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Angina pectoris, myocardial infarction

Interventions

Percutaneous 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-dilatation. 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(s)

Mean minimal lumen diameter at follow-up angiography.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Funder(s)

Funder type
Industry

Funder Name
Diagram B.V. (The Netherlands)

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?
Results article	results	01/07/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes