Ongoing 2b/3a inhibition In Myocardial infarction Evaluation.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20108

Source
NTR

Brief title
On-TIME 2

Intervention

Outcome measures

Primary outcome

To investigate the effect of upfront pre-treatment with a high bolus dosage of Tirofiban on the extent of residual ST segment deviation 1 hour after Primary Coronary Angioplasty for acute myocardial infarction, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

Secondary outcome

1. To investigate the effect of upfront pre-treatment with a high bolus dosage of Tirofiban on the incidence of TIMI 3 flow of the infarct related vessel (IRV) at initial angiography, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel);

2. To investigate the effect of upfront pre-treatment with a high bolus dosage of Tirofiban on the incidence of normal myocardial perfusion as assessed by Myocardial Blush Grade scoring immediately after primary angioplasty, compared to no pre-treatment (besides Aspirin,

Heparin and 600 mg of Clopidogrel);

3. To investigate the effect of upfront pre-treatment with a high bolus dosage of Tirofiban on infarct size as assessed by a single cTnT measurement performed 48-72 hours after Primary Coronary Angioplasty for acute myocardial infarction, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel);

4. To investigate the effect of upfront pre-treatment with a high bolus dosage of Tirofiban on the incidence of the combined occurrence of death, recurrent MI, urgent TVR, or thrombotic bailout at 30 days follow-up, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel);

5. To investigate the effect of upfront pre-treatment with a high bolus dosage of Tirofiban on the incidence of major bleeding (according to the most recent TIMI criteria), compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

Study description

Background summary

Possible other participating centres: br>
The Netherlands:

UMCG Groningen, Dpt of Cardiology, Dr. F. Zijlstra, MD, PhD.;

Germany:

Klinikum Schweinfurt, Dpt of Cardiology, Prof. Seggewiss;

Klinikum Coburg, Dpt of Cardiology, Prof. Brachmann;

Städstische Kliniken a.N. Esslingen, Dpt od Cardiologie, Prof. Leschke;

Herzzentrum Bad Krozingen, Prof. Neumann;

Klinikum Lüdenscheid. Dpt of Cardiology, Dr. Lemke, MD, PhD;

Klinikum Krefeld, Dpt of Cardiology, Prof. Späh;

Evangelisches Krankenhaus Düsseldorf, Dpt of Cardiology, Prof. Vester;

Kliniken der Ruhr-Universität Bochum, Dpt Cardiology, Prof. Mügge;

Essener Herzinfarktverbund, 4 Essener Kliniken;

Der Charité - Universitätsmedizin Berlin, Dpt of Cardiology, Dr. Möckel MD, PhD. (Dr. Dwäre MD, PHD.);

Städtisches Klinikum Kiel, Dpt of Cardiology, Prof. Buchwald;

Universitätsklinikum Lübeck, Dpt of Cardiology, Prof. Schunkert;

Herzzentrum Brandenburg in Bernau, Dr. Butter, MD, PhD;

Universitätsklinikum Röstock, Dpt of Cardiology, Prof. Nienaber;

Belgium:

CHR de la Citadelle Liège, Dpt of Cardiology, Dr. Jean Boland;

Poland:

University Hospital Poznan, Dpt of Cardiology, Dr. Lesiak, MD, PhD;

Study objective

Primary:

Upfront pre-treatment with a high bolus dosage of Tirofiban will result in a lower extent of residual ST segment deviation 1 hour after Primary Coronary Angioplasty for acute myocardial infarction, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

Secondary:

1. Upfront pre-treatment with a high bolus dosage of Tirofiban will result in a higher incidence of TIMI 3 flow of the infarct related vessel (IRV) at initial angiography, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

2. Upfront pre-treatment with a high bolus dosage of Tirofiban will result in a higher incidence of normal myocardial perfusion as assessed by Myocardial Blush Grade scoring on immediately after primary angioplasty, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

3. Upfront pre-treatment with a high bolus dosage of Tirofiban will result in a smaller infarct size as assessed by a single cTnT measurement performed 48-72 hours after Primary Coronary Angioplasty for acute myocardial infarction, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

4. Upfront pre-treatment with a high bolus dosage of Tirofiban will result in a lower incidence of the combined occurrence of death, recurrent MI, urgent TVR or thrombotic bailout at 30 days follow-up, compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

5. Upfront pre-treatment with a high bolus dosage of Tirofiban will not result in a higher incidence of major bleeding (according to the most recent TIMI criteria), compared to no pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

Study design

N/A

Intervention

1. Pre-treatment with a high bolus dosage of Tirofiban (25 ìg/kg bolus);

2. No pre-treatment (besides Aspirin, Heparin and 600 mg of Clopidogrel).

Contacts

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Eligibility criteria

Inclusion criteria

1. Symptoms of acute myocardial infarction of more than 30 minutes;

2. ST segment elevation of > 1 mV in 2 adjacent ECG leads, with cumulative ST segment deviation of 6 mm or more.
Ability to perform PCA within 6 hours after onset of symptoms.

Exclusion criteria

1. Patient with a contraindication to anticoagulation:

a. Present bleeding disorder including gastrointestinal bleeding, hematuria, or known presence of occult blood in the stool prior to randomization.

b. Systolic blood pressure persistently exceeding 200 mm Hg and/or diastolic blood pressure exceeding 110 mm Hg at time of enrollment.

c. Recent (<6 mnd) Stroke or Transient Ischemic Attack;

2. Patients with severe renal failure (hemodialysis);

3. Patient with recent (< 30 days) major surgery;

4. Participation in another clinical study one year before enrollment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2004
Enrollment:	950
Type:	Actual

Ethics review

Positive opinion

Date:	03-08-2005
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	NL46
NTR-old	NTR74
Other	: N/A
ISRCTN	ISRCTN06195297

Study results

Summary results

N/A