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

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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...

Ethische beoordeling	Positief advies
Status	Geen deelnemers meer gezocht
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20108

Bron
NTR

Verkorte titel
On-TIME 2

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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;

Doel van het onderzoek

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).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Algemeen / deelnemers

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Dokter Stolteweg 96

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

Wetenschappers

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Toewijzing op basis van loting
Blindering:	Dubbelblind
Controle:	Nepmedicijn

Deelname

Nederland

Status:	Geen deelnemers meer gezocht
(Verwachte) startdatum:	03-04-2004
Aantal proefpersonen:	950
Type:	Onderzoek is gestart

Ethische beoordeling

Positief advies

Datum:	03-08-2005
Soort:	Eerste beoordeling onderzoek

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL46
NTR-old	NTR74
Ander register	: N/A
ISRCTN	ISRCTN06195297

Resultaten

Samenvatting resultaten
N/A