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Ongoing 2b/3a inhibition In Myocardial infarction Evaluation

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2019	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

N/A

Study information

Scientific Title
Ongoing 2b/3a inhibition In Myocardial infarction Evaluation

Acronym
On-TIME 2

Study objectives
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).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Medical Ethics Review Committee (METC) of the Isala Ziekenhuizen of Zwolle (Netherlands)

Study design
Multinational multicenter double-blind placebo-controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Acute myocardial infarction

Interventions
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)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tirofiban

Primary outcome measure
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 measures
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).

Overall study start date
03/04/2004

Completion date
01/01/2007

Eligibility

Key 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
3. Ability to perform PCA within 6 hours after onset of symptoms

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
950

Key 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 randomisation
b. Systolic blood pressure persistently exceeding 200 mm Hg and/or diastolic blood pressure exceeding 110 mm Hg at time of enrolment
c. Recent (<6 mnd) Stroke or Transient Ischemic Attack
2. Patients with severe renal failure (hemodialysis)
3. Patient with recent (< 30 days) major surgery
Participation in another clinical study one year before enrolment

Date of first enrolment
03/04/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Diagram B.V.
Zwolle
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Sponsor information

Organisation
Diagram B.V. (Netherlands)

Sponsor details
Van Nahuysplein 6
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Sponsor type
Industry

ROR
https://ror.org/03rhyyh86

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme BV (MSD) (Germany)

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	16/08/2008		Yes	No
Results article	results	01/06/2010		Yes	No
Results article	results	01/08/2011		Yes	No
Results article	results	01/05/2012		Yes	No
Other publications	subgroup analysis	01/10/2017		Yes	No
Results article	results	01/04/2019		Yes	No