

Ongoing 2b/3a inhibition In Myocardial infarction Evaluation

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/01/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J Klijn

Contact details
Diagram B.V.
Van Nahuysplein 6
Zwolle
Netherlands
8011 NB
+31 (0)38 4262997
j.klijn@diagram-zwolle.nl

Additional identifiers

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute myocardial infarction

Interventions

1. Pre-treatment with a high bolus dosage of Tirofiban (25 µg/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(s)

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).

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Netherlands

8011 NB

Sponsor information

Organisation

Diagram B.V. (Netherlands)

ROR

<https://ror.org/03rhyyh86>

Funder(s)

Funder type

Industry

Funder Name

Merck Sharp & Dohme BV (MSD) (Germany)

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	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
Results article	results	01/04/2019		Yes	No
Other publications	subgroup analysis	01/10/2017		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes