

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

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

## Study information

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

**Acronym**

## 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?
<a href="#">Results article</a>	results	16/08/2008		Yes	No
<a href="#">Results article</a>	results	01/06/2010		Yes	No
<a href="#">Results article</a>	results	01/08/2011		Yes	No
<a href="#">Results article</a>	results	01/05/2012		Yes	No
<a href="#">Results article</a>	results	01/04/2019		Yes	No
<a href="#">Other publications</a>	subgroup analysis	01/10/2017		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes