Trial Registration

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I receive salary support from The BMJ for my editorial duties.

No connections with other commercial interests
What’s the ICMJE?

- International Committee of Medical Journal Editors
- Meets annually to develop policy and consensus about matters relating to publication
- Recognized biased reporting as a problem

2013 ICMJE Meeting in Santiago, Chile
Publication Bias:

1. Selective Reporting

2. Non-reporting

3. Post-hoc analyses (not identified as such)
They decided to do something about it.

- ICMJE member journals would only consider **clinical trials** for publication that had been **prospectively registered** (2005)

- Many other journals followed
“Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”
Are surgery and surgical devices considered health interventions?

Yes.

"Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes)."
What are health outcomes?

Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.
Rationale for Trial Registration

We use evidence to guide our treatments

A randomized trial is the best method to establish evidence

Trial registration exists to make sure we have a record of exactly what we set out to study
# Tracking outcomes...

## Tracking Information

<table>
<thead>
<tr>
<th>First Received Date</th>
<th>January 7, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Updated Date</td>
<td>August 6, 2012</td>
</tr>
<tr>
<td>Start Date</td>
<td>July 2008</td>
</tr>
<tr>
<td>Primary Completion Date</td>
<td>November 2011</td>
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</tbody>
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**Current Primary Outcome Measures**

[submitted: August 6, 2012]

- Percent Diameter Stenosis of the Culprit Lesion Following the First Bolus of Study Drug Prior to Primary Percutaneous Coronary Intervention [Time Frame: Following the First Bolus of Study Drug Prior to Primary Percutaneous Coronary Intervention] [Designated as safety issue: Yes]
- Angiographic characteristics of the culprit lesion [Time Frame: Prior to index hospitalization discharge and at 30 days] [Designated as safety issue: Yes]
- Measurements of epicardial flow and myocardial perfusion in the territory of the infarct-related artery [Time Frame: At the time of catheterization for the STEMI] [Designated as safety issue: No]

**Original Primary Outcome Measures**

[submitted: January 17, 2008]

- Number of Patients With Decrease in Thrombus Grade in the Culprit Artery Following the First Bolus of Study Drug Prior to Primary Percutaneous Coronary Intervention [Time Frame: Following the First Bolus of Study Drug Prior to Primary Percutaneous Coronary Intervention] [Designated as safety issue: No]
- Number of Patients With Thrombolysis in Myocardial Infarction (TIMI) Myocardial Perfusion Grade (TMPG) of 2 or 3 in the Territory of the Culprit Artery Following Primary Percutaneous Coronary Intervention Prior to Second Bolus of the Study Drug [Time Frame: Following Primary Percutaneous Coronary Intervention Prior to Second Bolus of the Study Drug] [Designated as safety issue: No]

**Change History**

Complete list of historical versions of study NCT03604629 on ClinicalTrials.gov Archive Site

## Current Secondary Outcome Measures

[submitted: August 6, 2012]

- Number of Patients With Decrease in Thrombus Grade in the Culprit Artery Following the First Bolus of Study Drug Prior to Primary Percutaneous Coronary Intervention [Time Frame: Following the First Bolus of Study Drug Prior to Primary Percutaneous Coronary Intervention] [Designated as safety issue: No]
- Number of Patients With Thrombolysis in Myocardial Infarction (TIMI) Myocardial Perfusion Grade (TMPG) of 2 or 3 in the Territory of the Culprit Artery Following Primary Percutaneous Coronary Intervention Prior to Second Bolus of the Study Drug [Time Frame: Following Primary Percutaneous Coronary Intervention Prior to Second Bolus of the Study Drug] [Designated as safety issue: No]
- Corrected Thrombolysis in Myocardial Infarction (TIMI) Frame Count (cTFC) in the culprit artery
- Measurements of Flow Velocity in the Culprit Artery in Terms of Corrected Thrombolysis in Myocardial Infarction (TIMI) Frame Count (cTFC) [Time Frame: Following Primary Percutaneous Coronary Intervention Prior to Second Bolus of the Study Drug] [Designated as safety issue: No]
- Corrected Thrombolysis in Myocardial Infarction (TIMI) Frame Count (cTFC) of Less Than 14 [Time Frame: Following Primary Percutaneous Coronary Intervention Prior to Second Bolus of the Study Drug] [Designated as safety issue: No]

**Original Secondary Outcome Measures**

[submitted: January 17, 2008]

- Safety Endpoint: Number of Patients Who Developed Thrombolysis In Myocardial Infarction (TIMI) Minor Bleeding [Time Frame: Through 30 days following PPC] [Designated as safety issue: Yes]
- Safety Endpoint: Number of Patients Who Developed Thrombolysis In Myocardial Infarction (TIMI) Minimal Bleeding [Time Frame: Through 30 days following primary percutaneous coronary intervention] [Designated as safety issue: Yes]
- Safety Endpoint: Number of Patients Who Developed Cardiac Arrhythmias [Time Frame: Through 30 days following primary percutaneous coronary intervention] [Designated as safety issue: Yes]
- Safety Endpoint: Number of Deaths [Time Frame: Through 30 days following primary percutaneous coronary intervention] [Designated as safety issue: Yes]
- Safety endpoints including the incidence of death, recurrent MI, abrupt vessel closure, subacute stent thrombosis, and TIMI Major and Minor Bleeding [Time Frame: At hospital discharge and at 30 days] [Designated as safety issue: Yes]
The registry must be:

- In WHO International Clinical Trials Registry Platform (ICTRP)
- Accessible to the public at no charge
- Accessible worldwide
- Managed by a not-for-profit organization
- Able to ensure validity
- Electronically searchable
ICMJE recommendations for trial registration

- Occur before enrollment
- Registration number at the end of abstract
- Results should be posted in trial registries
  - FDAAA does require results posting for some trials
  - Desirable for all!

Thank you!
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