

# Trial Registration

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# Disclosures

- I am employed by the Brigham and Women's Physician Organization
- 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

2013 ICMJE Meeting in Santiago, Chile



- Meets annually to develop policy and consensus about matters relating to publication
- **Recognized biased reporting as a problem**

# 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

# What is a trial?

“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**

# www.clinicaltrials.gov

## ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. [Learn more about clinical studies](#) and [about this site](#), including relevant [history](#), [policies](#), and [laws](#).

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ClinicalTrials.gov currently lists **178,655 studies** with locations in all 50 states and in **187 countries**.

Text Size ▾

### Search for Studies

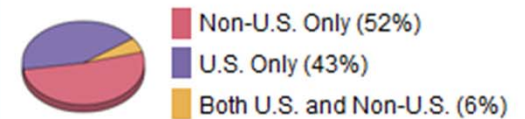
Example: "Heart attack" AND "Los Angeles"

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Total N = 34,132 studies  
Data as of November 13, 2014

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# Tracking outcomes...

Tracking Information	
First Received Date <small>ICMJE</small>	January 7, 2008
Last Updated Date	August 6, 2012
Start Date <small>ICMJE</small>	July 2008
Primary Completion Date	November 2011 (final data collection date for primary outcome measure)
Current Primary Outcome Measures <small>ICMJE</small> (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: No ]
Original Primary Outcome Measures <small>ICMJE</small> (submitted: January 17, 2008) 	<ul style="list-style-type: none"> <li>- angiographic characteristics of the culprit lesion [ Time Frame: Prior to index hospitalization discharge and at 30days. ] [ Designated as safety issue: Yes ]</li> <li>- 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 ]</li> </ul>
Change History	Complete list of historical versions of study NCT00604695 on <a href="http://ClinicalTrials.gov">ClinicalTrials.gov Archive Site</a>
Current Secondary Outcome Measures <small>ICMJE</small> (submitted: August 6, 2012) 	<ul style="list-style-type: none"> <li>- 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 ]</li> <li>- 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 ]</li> <li>Thrombolysis In Myocardial Infarction (TIMI) Myocardial Perfusion Grade (TMPG) of 2 or 3 in the territory of the culprit artery</li> <li>- 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 ]</li> <li>Corrected Thrombolysis In Myocardial Infarction (TIMI) Frame Count (cTFC) in the culprit artery</li> <li>- Number of Patients With Hyperemic Flow in the Culprit Artery. That is 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 ]</li> <li>Corrected Thrombolysis In Myocardial Infarction (TIMI) Frame Count (cTFC) of less than 14</li> <li>- Safety Endpoint: Number of Patients Who Developed Thrombolysis In Myocardial Infarction (TIMI) Minor Bleeding [ Time Frame: Through 30days following PPCI ] [ Designated as safety issue: Yes ]</li> <li>- Safety Endpoint: Number of Patients Who Developed Thrombolysis In Myocardial Infarction (TIMI) Minimal Bleeding [ Time Frame: Through 30days following primary percutaneous coronary intervention ] [ Designated as safety issue: Yes ]</li> <li>- Safety Endpoint: Number of Patients Who Developed Cardiac Arrhythmias [ Time Frame: Through 30days following primary percutaneous coronary intervention ] [ Designated as safety issue: Yes ]</li> <li>- Safety Endpoint: Number of Deaths [ Time Frame: Through 30days following primary percutaneous coronary intervention ] [ Designated as safety issue: Yes ]</li> </ul>
Original Secondary Outcome Measures <small>ICMJE</small> (submitted: January 17, 2008) 	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 30days. ] [ 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!



International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals [Accessed 11/13/2014] Available from: <http://www.ICMJE.org>.

Thank you!

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