Design and rationale of the TOTAL trial: A randomized trial of routine aspiration ThrOmbecTomy with percutaneous coronary intervention (PCI) versus PCI Alone in patients with ST-elevation myocardial infarction undergoing primary PCI

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Background A major limitation of primary percutaneous coronary intervention (PPCI) for the treatment of ST-elevation myocardial infarction (STEMI) is impaired microvascular perfusion due to embolization and obstruction of microcirculation with thrombus. Manual thrombectomy has the potential to reduce distal embolization and improve microvascular perfusion. Clinical trials have shown mixed results regarding thrombectomy.

Objective The objective of this study is to evaluate the efficacy of routine upfront manual aspiration thrombectomy during PPCI compared with percutaneous coronary intervention alone in patients with STEMI.

Design This is a multicenter, prospective, open, international, randomized trial with blinded assessment of outcomes. Patients with STEMI undergoing PPCI are randomized to upfront routine manual aspiration thrombectomy with the Export catheter (Medtronic CardioVascular, Santa Rosa, CA) or to percutaneous coronary intervention alone. The primary outcome is the composite of cardiovascular death, recurrent myocardial infarction, cardiogenic shock, or new or worsening New York Heart Association class IV heart failure up to 180 days. The trial uses an event-driven design and will recruit 10,700 patients.

Summary The TOTAL trial will determine the effect of routine manual aspiration thrombectomy during PPCI on clinically important outcomes. (Am Heart J 2014;167:315-321.e1.)

Noninvasive measures of tissue reperfusion such as ST-segment resolution have also been clearly associated with mortality after PPCI.4

Removal of thrombus before percutaneous coronary intervention (PCI) may reduce distal embolization and microvascular obstruction. A single-center trial, the TAPAS trial (N = 1,071), demonstrated that routine use of manual aspiration with the Export catheter (Medtronic CardioVascular, Santa Rosa, CA) compared with PCI alone during PPCI reduced the incidence of the primary outcome of impaired microvascular perfusion (MBG 0 or 1, 17.1% vs 26.3%, \( P < .001 \)).5 This modest improvement in a surrogate outcome was associated with a significant 52% reduction in mortality at 1 year.6 After the publication of this trial, both the European Society of Cardiology and American College of Cardiology/American Heart Association guidelines included a class IIa recommendation for the use of routine thrombectomy during PPCI.7,8

However, a recent multicenter randomized trial (INFUSE AMI, N = 452) demonstrated that manual aspiration with the Export catheter in patients with anterior infarcts did not reduce infarct size in patients undergoing PPCI compared with PCI alone.9 In addition, a recent meta-analysis of randomized trials found that thrombectomy may be associated with an increased risk of stroke,10 possibly due to lack of guide catheter engagement during removal of thrombus and embolization to the cerebral circulation. However, these findings are based on a small number of events and thus may be unreliable. These differing findings for efficacy and safety in relatively underpowered trials underscore the need for a definitive, large, multicenter trial of routine thrombectomy during PPCI.

To determine feasibility of a large randomized trial, we performed an international survey of interventional cardiologists showing that 89% thought a large, randomized open-label trial with blinded outcome assessment, comparing routine upfront manual aspiration thrombectomy with the Export catheter with PCI with PCI alone in patients undergoing PPCI for STEMI.

### Table I. Eligibility criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<td>1. Patients presenting with:</td>
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<tr>
<td>- Symptoms of myocardial ischemia lasting for ( \geq 30 \text{ min} )</td>
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<td>- Definite ECG changes indicating STEMI: ST elevation of ( \geq 0.1 \text{ mV} ) in 2 contiguous limb leads or ( \geq 0.2 \text{ mV} ) in 2 contiguous precordial leads</td>
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<td>2. Referred for PPCI for presenting symptoms</td>
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<td>3. Randomized within 12 h of symptoms onset and before diagnostic angiography</td>
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<td>4. Informed consent</td>
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<table>
<thead>
<tr>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>1. Age ( \leq 18 \text{ y} )</td>
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<tr>
<td>2. Prior CABG surgery</td>
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<tr>
<td>3. Life expectancy &lt;6 months due to noncardiac condition</td>
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<td>4. Treatment with fibrinolytic therapy for qualifying index STEMI event</td>
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Abbreviation: CABG, Coronary artery bypass graft.

### Hypothesis

Manual thrombectomy may reduce distal embolization of thrombus and thus may prevent no reflow and improve myocardial perfusion in patients undergoing PPCI. By preventing no reflow and improving microvascular perfusion, thrombectomy may prevent death, acute cardiogenic shock, and subsequent heart failure events. By reducing thrombus burden at site of stent implantation, thrombectomy may prevent stent thrombosis and MI.

### Design

TOTAL is a multinational, multicenter, parallel randomized open-label trial with blinded outcome assessment, comparing routine upfront manual aspiration thrombectomy with the Export catheter with PCI with PCI alone in patients undergoing PPCI for STEMI.

### Eligibility criteria

Patients presenting with STEMI within 12 hours of symptom onset and referred for PCI are eligible for inclusion (Table I). Exclusion criteria include prior coronary artery bypass surgery or patients treated with fibrinolytic therapy for index STEMI (see Table I for full list of inclusion and exclusion criteria).

### Operator requirements

Interventional cardiologists participating in the TOTAL trial are required to have annual PCI volumes as recommended by American College of Cardiology/American Heart Association guidelines (elective PCI volume of 75 PCI per year and STEMI PCI volume of 11 per year).12 In addition, they must be experienced at manual thrombectomy (ie, having performed \( \geq 5 \) thrombectomy procedures in the last 2 years).
Randomization
Using a computerized central randomization service located at the coordinating center in Hamilton, Canada, patients are randomized 1:1 to either manual aspiration thrombectomy followed by PCI or PCI alone with stratification by study center. Patients are considered to be randomized as soon as the treatment allocation is provided to the site.

Treatment groups
1. Upfront (immediately after wire crossing) aspiration thrombectomy with the Export catheter followed by PCI
2. PCI alone

Thrombectomy procedure
A minimum of 6F guiding catheters (minimum internal diameter 0.070 in) is required for patients undergoing thrombectomy. After the lesion is crossed with a wire, the Export thrombectomy catheter is advanced and positioned proximal to the lesion, at which point aspiration is started before crossing the lesion. It is recommended that the thrombectomy catheter be passed through the lesion multiple times such that a minimum of 2 syringes are filled with aspirated blood and thrombus material (≥40 mL in total). If at any time, aspiration stops suddenly, the thrombectomy catheter should be removed to check for a large thrombus obstructing the lumen. If there is a residual angiographic thrombus after thrombectomy, thrombectomy may be repeated as judged necessary.

If the thrombectomy catheter does not cross the target lesion, it is recommended that predilation be performed with a small diameter balloon catheter (≤2.00 mm diameter) and that thrombectomy be reattempted. After thrombectomy, aspiration of the guide catheter is recommended to remove air or residual thrombus. After aspiration thrombectomy, the PCI procedure should be performed as per local practice.

After thrombectomy is performed, the guide catheter should be engaged properly in coronary ostium when aspiration catheter is removed. In addition, it is recommended that the guide catheter be aspirated to remove air or thrombus that may have been left in guide catheter after thrombectomy use.

Locally approved Export catheters including the XT, AP, and ADVANCE may be used in the trial, and both 6F and 7F Export catheters are allowed. The type of Export catheter used is recorded on the case report forms.

To enhance patient safety, bailout thrombectomy is allowed after a failure of the initial PCI alone strategy, defined as either (i) TIMI 0 or 1 flow with large thrombus after balloon predilation or (ii) large thrombus persisting after stent deployment.

Study outcomes
Primary outcome
The primary outcome is the composite of cardiovascular death, recurrent MI, cardiogenic shock, or new or worsening NYHA class IV heart failure occurring within 180 days of randomization (Table II).

Key secondary outcomes
The key secondary efficacy outcome is the composite of cardiovascular death, MI, cardiogenic shock, new or worsening class IV heart failure, stent thrombosis and target vessel revascularization up to 180 days. The key safety outcome is stroke up to 30 days, and the key net benefit outcome is the composite of cardiovascular death, recurrent MI, stroke, cardiogenic shock, or new or worsening NYHA class IV heart failure up to 1 year. Another key secondary outcome is cardiovascular mortality up to 180 days.

Central events adjudication
A committee of clinicians blinded to treatment allocation will adjudicate all components of primary outcome as well as stent thrombosis, transient ischemic attack, stroke, target vessel revascularization and major bleeding.

The TOTAL trial is an investigator-initiated trial. Funding for the TOTAL trial was provided by Canadian Network and Center for Trials Internationally, Canadian Institutes of Health Research, and Medtronic CardioVascular. The OCT substudy was funded by St Jude Medical (Minneapolis, MN).

Statistical considerations
The sample size calculation is based on a time-to-event analysis, 180 days of follow-up for the primary outcome, 80% power, and a 2-sided 5% type I error level. To ensure adequate power, the sample size was adjusted for nonadherence rates: an estimated crossover from thrombectomy to PCI alone of 3% and an estimated cross-in from PCI alone to thrombectomy of 3% during index procedure. The estimated sample size was increased by a further 8% to account for patients randomized but who do not undergo PCI.

The originally estimated sample size was 4,000 patients with 430 primary outcome events being needed to detect a relative risk reduction (RRR) of 25%, assuming a 14% rate of the primary outcome in the control group at 6 months of follow-up. As the trial progressed, the trial protocol was amended to render the trial event driven to ensure an adequately powered trial with a requirement for 450 primary outcome events with a maximum sample size of 7,000 patients.
## Table II. Outcome definitions

The primary outcome is the composite of cardiovascular death, recurrent MI, cardiogenic shock, or new or worsening NYHA class IV HF up to 180 d of follow-up (first occurrence, time-to-event variable)

<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Cardiovascular death</td>
<td>Death will be classified as cardiovascular or noncardiovascular. All deaths with a clear cardiovascular or unknown cause will be classified as cardiovascular. Only deaths due to a documented noncardiovascular cause (eg, cancer) will be classified as noncardiovascular.</td>
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<tr>
<td>Recurrent MI</td>
<td>Recurrent MI will be subdivided into MI within the first 24 h of randomization, between 24 h and 7 d after randomization, and &gt;7 d after randomization.</td>
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<td>MI occurring within 24 h of randomization</td>
<td>Recurrent ischemic symptoms &gt;20 min with new ST elevation &gt;0.1 mV in ≥2 contiguous leads not due to changes from evolution of the index MI. Ischemic symptoms &gt;20 min and either (i) elevation or re-elevation of cardiac biomarkers (CK-MB or troponin) greater than twice the ULN and if already elevated, then further elevations &gt;50% above a previous value that was decreasing or (ii) new ST-segment elevation or new significant Q waves in ≥2 contiguous leads, which are separate from the baseline MI.</td>
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<tr>
<td>MI occurring between 24 h and 7 d of randomization</td>
<td>Typical rise and fall of biochemical markers of myocardial necrosis to greater than twice the ULN or if markers were already elevated, further elevation of a marker to &gt;50% of a previous value that was decreasing and &gt;2x ULN, with ≥1 of the following: (i) ischemic symptoms, (ii) development of new pathologic Q waves, or (iii) ECG changes of new ischemia or (iv) pathologic evidence of MI.</td>
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<tr>
<td>MI occurring after 7 d of randomization</td>
<td>MI occurring within 24 h after nonindex PCI that is performed &gt;24 h after randomization Cardiac biomarker (CK-MB or troponin) &gt;3x the ULN or increased by 50% from the preprocedural valley level and ≥3 times ULN in patients with already elevated enzymes or new ST-segment elevation or development of significant Q waves in ≥2 contiguous leads, which are discrete from baseline MI.</td>
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<tr>
<td>Cardiogenic shock</td>
<td>Cardiogenic shock is defined as systolic blood pressure &lt;90 mm Hg not responsive to fluid resuscitation and/or heart rate correction for ≥1 h and believed to be secondary to cardiac dysfunction and associated with ≥1 of the following: (1) signs of pulmonary edema, (2) signs of hypoperfusion (cool clammy skin, oliguria, or altered sensorium), or (3) cardiac index &lt;2.2 L/min. In patients presenting with cardiogenic shock at the time of randomization, they must have a ≥24-h period with complete resolution of shock and a new cardiogenic shock event (ie, due to new stent thrombosis) for this event to be eligible as a primary outcome event.</td>
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<tr>
<td>New or worsening NYHA class IV HF</td>
<td>New or worsening NYHA class IV HF is defined as a physician decision to treat HF with IV diuretic, inotropic agent, or vasodilator plus ≥1 of the following: (1) presence of pulmonary edema or pulmonary vascular congestion on chest radiograph thought to be due to HF, (2) serial changes reaching above the lower 1/3 of the lung fields thought to be due to HF, or (3) PCWP or LVEDP &gt;18 mm Hg. To be defined as &quot;new or worsening,&quot; the HF as defined above, must not have been present at the time of randomization but have occurred ≥6 h after randomization. In the case of NYHA class IV HF occurring as an outpatient, readmission to an acute care facility is required in addition to the above criteria.</td>
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<td>Stroke</td>
<td>Any stroke is defined as the presence of a new focal neurologic deficit thought to be vascular in origin, with signs or symptoms lasting ≥24 h. It is strongly recommended (but not required) that an imaging procedure such as a computed tomography or magnetic resonance imaging be performed.</td>
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<td>TVR</td>
<td>TVR is defined as any revascularization procedure (PCI or CABG) involving the vessel treated during the index PCI procedure for STEMI.</td>
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Abbreviations: HF, Heart failure; CK-MB, creatine kinase-MB; ULN, upper limit of normal; PCWP, pulmonary capillary wedge pressure; LVEDP, left ventricular end-diastolic pressure; TVR, target vessel revascularization.
In October 2013, based on data external to the trial (TASTE trial results), the steering committee (online Appendix) felt that a 20% RRR was clinically important and possible.\(^6\) Well-established therapies such as aspirin are associated with approximately a 20% RRR. As a result, the steering committee amended the protocol for the trial to have 80% power for a 20% RRR, which requires 718 events. Based on blinded overall event rate of 7% provided by data monitoring committee and adjusting for a no-PCI rate of 8%, it is estimated that approximately 10,700 patients will be randomized.

For the primary analysis, a modified intention-to-treat analysis will include all randomized patients who have undergone PCI for index STEMI. Patients will be kept in the treatment group to which they were originally randomized. Patients who do not undergo PCI for the index STEMI (ie, normal coronary arteries) will not be included in the primary analysis.

A 2-sided, log-rank test will be used to determine if there is a significant difference between the outcome rates in the 2 treatment groups at the 5% significance level. The hazard ratio (HR) and its 95% CI will be estimated using a Cox proportional hazards regression model with treatment group as a predictor variable.

Subgroup analysis

There will be 1 primary subgroup analysis based on the TIMI thrombus grade (<3 vs ≥3) determined after first injection of infarct artery before wire crossing. The hypothesis is that thrombectomy may be more beneficial in patients with high thrombus burden. Other exploratory a priori secondary subgroups will include the following: symptom onset (<6, 6-12 hours), initial TIMI flow (0-1, 2-3), age (≤65, >65 years), tertiles of center PPCI volume, and MI type (anterior, nonanterior).

Substudies

**Electrocardiographic substudy.** Presentation and post-PCI electrocardiographic (ECGs) (30-60 minutes post-PCI) of all study participants will be analyzed. Location of ST elevation, dynamic ECG changes, pathologic Q waves, grade of ischemia, and heart rhythm will be interpreted from all ECGs according to previous publications.\(^4\) Dynamic ECG changes are defined by 2 distinct ECG patterns: the preinfarction syndrome as ST elevation accompanied by positive T waves and evolving MI as pathologic Q waves and/or negative T wave. From the post-PCI ECG, the degree of ST elevation in the lead with the maximal changes at baseline, T-wave amplitude in the same lead and ST-segment resolution, defined as >70% compared with the baseline ECG, will be assessed. This large data set will enable the validation of ECG correlates of microvascular function after PPCI. Specifically, the substudy will determine whether the dynamic ECG changes predict outcomes better than the traditional marker of >70% ST-segment resolution. In addition, the substudy will help provide mechanistic information about possible benefits of thrombectomy on ECG measures of microvascular perfusion.

**Angiographic core laboratory and angiographic substudy.** The TOTAL angiographic substudy will compare the efficacy of routine aspiration thrombectomy in restoring epicardial and myocardial reperfusion in STEMI PPCI. Angiographic assessment will be performed by an independent core laboratory blinded to patient details and treatment assignment. The primary aim of the TOTAL angiographic substudy will be to assess the extent of angiographic myocardial reperfusion by MBG between patients randomized to aspiration thrombectomy with PCI compared with PCI alone.\(^17\) Impaired tissue reperfusion defined by MBG of 0 to 1, found in up to 30% of patients with TIMI 3 flow after PCI, is independently associated with increased mortality.\(^3\) Myocardial blush grade quantification will be performed by visual qualitative assessment of cineangiograms post-PCI by 2 independent readers, with discrepant results being read by a third reader. Secondary aims include assessment of the thrombus burden in the infarct-related artery and post-PPCI reflow by TIMI thrombus grade and TIMI flow grade between the 2 treatment strategies, respectively.\(^19\) Assessment of collateral vessels to area at risk by Rentrop criteria will also be compared between the 2 groups.\(^2\) Finally, the angiographic core laboratory will also evaluate the incidence of bailout thrombectomy in the PCI only arm and nonadherence to the use of thrombectomy in the thrombectomy arm.

**Cardiac magnetic resonance imaging substudy.** The cardiac magnetic resonance imaging (CMR) substudy hypothesis is that manual thrombectomy will reduce the degree of microvascular obstruction (primary outcome) in patients undergoing PPCI. Second, we hypothesize that manual thrombectomy will lead to improved infarct characteristics, namely, (1) peri-infarct region, (2) infarct size, (3) myocardial hemorrhage, even in the absence in decrease in left ventricular function or myocardial necrosis.

Sample size calculation is based on expected differences in microvascular obstruction. With a standardized effect size of 0.5, we expect to require 63 subjects per group to reliably detect a significant difference at 2-tailed \(\alpha\) of .05 and \(\beta\) of .2. However, to adjust for uncertainties in our assumptions, the sample size has been increased by 20% to 150 patients. Beyond traditional imaging markers, end points of the CMR substudy will include differences in thrombectomy followed by PCI versus PCI alone for the following: (1) percent microvascular obstruction, (2) percent salvaged myocardium, (3) percent arrhythmogenic peri-infarct region, (4) percent myocardial necrosis, and (5) percent myocardial hemorrhage.

**Optical coherence tomography substudy.** An optical coherence tomography (OCT) substudy will be
conducted to investigate thrombus removal and OCT-guided PCI optimization in the setting of STEMI. Optical coherence tomography is a high-resolution intravascular imaging technique that is more sensitive for the detection of thrombus compared with intravascular ultrasound and conventional angiography. Optical coherence tomography also shows promise as a modality to assist in optimization of the PCI procedure by providing a detailed overview of the vessel pathology before stenting and evaluating the stent result.

Patients in the substudy will undergo OCT imaging of the culprit coronary artery after restoration of TIMI 2 to 3 flow and also after an angiographically optimized stent implantation. The quantity of residual thrombus before and after stenting will be compared between patients undergoing manual aspiration thrombectomy and standard PCI and will be assessed by measuring percent thrombus burden. Thrombus burden is defined as the mean of the thrombus area divided by lumen area over the arterial segment defined by the final stent length. Based on data from the first 20 patients enrolled in the TOTAL OCT substudy, we estimate a control presten thrombus burden of 12% and SD of 11.6%. Therefore, a sample size of 163 patients would have 84% power to detect a 30% reduction in thrombus burden with thrombectomy. Assuming 90% of OCT patients have analyzable prestent imaging, we plan to enroll 180 to 200 patients in the substudy to ensure adequate power to evaluate differences in thrombus burden between the thrombectomy and standard PCI groups. In addition, operators will follow prespecified optimization criteria for OCT-guided PCI. The angiographic and clinical outcomes of this cohort will be compared with a matched group of patients undergoing angiographically guided PCI as part of the TOTAL trial.

Discussion

The TOTAL trial will definitively determine the effect of routine thrombectomy on important clinical outcomes during PPCI. TOTAL is an event-driven trial and as a result will be appropriately powered for the primary outcome.

TASTE trial

The TASTE trial (N = 7,244) was a registry-based trial that randomized patients within 24 hours of onset of STEMI who were referred for PCI to aspiration thrombectomy versus PCI alone. The trial was initially designed to have 80% power to detect a 30% reduction in all-cause mortality with 456 events needed. The event rates were lower than planned, and despite increasing sample size from 5,000 to 7,244, they only had 213 of 456 planned events. This shortfall in number of events and resultant lack of study power should make clinicians cautious about excluding a clinically important treatment effect.

The rates of the primary outcome of mortality at 30 days (2.8% vs 3.0%, HR 0.94, 95% CI [0.72-1.22]) were not different between the groups. There were nonsignificant trends toward reduction of MI (HR 0.61, 95% CI [0.34-1.07]) and stent thrombosis (HR 0.57, 95% CI [0.20-1.02]) with thrombectomy. The trial demonstrates the challenge of powering a trial for mortality when control event mortality in STEMI is only 3%. We must remember that historically, treatment effects of 20% to 25% are likely for most therapies. Twenty-five years ago, the ISIS 2 trial required 17,000 patients to show that aspirin (23% RRR) and streptokinase (25% RRR) reduced mortality compared with placebo when control mortality rates were 12%. TASTE was underpowered for all-cause mortality, and future trials need to ensure adequate power.

Lessons learned from TASTE have informed the design of the TOTAL trial

The TOTAL trial was specifically designed as an event-driven trial to ensure that the trial was powered for the primary outcome. Furthermore, the primary outcome is a composite outcome of cardiovascular death, MI, cardiogenic shock, and class IV heart failure because all-cause mortality would require a trial of >30,000 patients, which was thought not to be feasible. Finally, the TOTAL trial is now powered for a 20% RRR for the primary outcome, which is a realistic treatment effect and is similar to the treatment effect of aspirin in STEMI.

Current thrombectomy use and implications

Data from the American College of Cardiology CathPCI Registry showed that thrombectomy was used in <1 in 5 patients with STEMI undergoing PPCI in the United States. In addition, our survey of interventional cardiologists showed that most believed that large confirmatory trials are needed after the TAPAS trial. As a result, the results of the TOTAL trial will have the potential to impact thrombectomy use and influence STEMI treatment worldwide.

Study status

As of December 2, 2013, recruitment is ongoing with 7,689 patients having been randomized at 79 centers in 19 countries.

Summary

The TOTAL trial is a large simple trial that is designed to assess the effect of routine manual thrombectomy with PCI compared with PCI alone on important clinical outcomes.

References


Appendix


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