
# Adjunctive, low-dose intracoronary recombinant tissue plasminogen activator (tPA) versus placebo for primary PCI in patients with ST-segment elevation myocardial infarction

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

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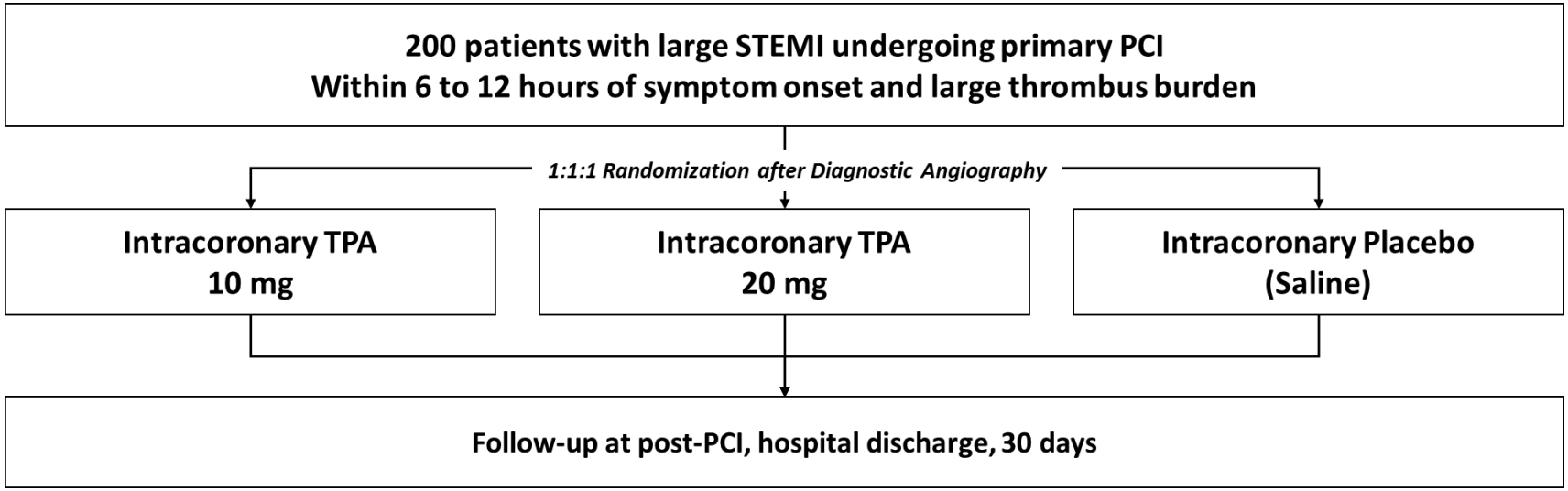
# STRIVE Study Design



# Study Design

A prospective, 3-arm, parallel group, blinded, randomized controlled trial.

STRIVE will enroll approximately 200 patients over 1.5 years.

Patients will be randomly allocated (1:1:1) to receive either 10 mg tPA, 20 mg tPA or placebo.

Patients will be followed at discharge and 30 days.

# Study Outcomes

## Primary Outcome:

Composite of post-procedural myocardial blush (MBG) grade 0/1 or distal embolization.

## Clinical Composite Outcomes:

Composite of cardiovascular death, myocardial re-infarction, cardiogenic shock or new onset heart failure at 30 days.

## Safety Outcome:

1. Major bleeding by 30 days.
2. Major or clinically significant bleeding by 30 days.

# Study Outcomes

## Secondary Outcomes:

1. Complete (≥50%) ST-segment resolution (worst lead) at 30 minutes post-PCI.
2. Each component of the primary outcome assessed separately.
3. All-cause mortality at 30 days.
4. Stroke at 30 days.
5. Flow velocity as measured by the corrected TIMI frame count.
6. Post-procedural TIMI flow grade 3.

## Other Outcomes:

1. Composite of cardiovascular death, cardiogenic shock and new onset heart failure at 30 days.
2. Composite of cardiovascular death, recurrent myocardial infarction, definite stent thrombosis, stroke, new onset heart failure at 30 days.

# Study Population: Inclusion Criteria

1. Patients with STEMI undergoing primary PCI
2. ECG changes indicating large territory STEMI (defined as ≥2mm ST-segment elevation in 2 contiguous anterior precordial leads; or ≥2mm ST-segment elevation in 2 inferior leads coupled with ST-segment depression in 2 contiguous anterior leads for a total ST-segment deviation of ≥8mm)
3. Randomization between 6 to 12 hrs of symptom onset
4. Large thrombus burden with angiographic TIMI Thrombus Grade ≥3 after wire crossing

# Study Population: Exclusion Criteria

1. Active internal bleeding or high risk of bleeding or any prior intracranial bleeding
2. Any other absolute or relative contraindication to fibrinolytic therapy
3. Administration of a fibrinolytic ≤24hrs prior to randomization
4. Cardiogenic shock
5. Left bundle branch block
6. Planned use of glycoprotein IIb/IIIa inhibitors
7. Any medical, geographic, or social factor making study participation impractical or precluding 6 month follow-up