



Platelet-Oriented Inhibition in New TIA and minor ischemic stroke (POINT) Trial

WHAT POINT is a prospective randomized, double-blind, multicenter clinical trial. The primary objective of POINT is to determine whether clopidogrel 75 mg/day taken after a loading dose of 600 mg is effective in preventing major ischemic vascular events (ischemic stroke, myocardial infarction, and ischemic vascular death) at 90 days when initiated within 12 hours of TIA or minor ischemic stroke onset in patients receiving aspirin 50-325 mg/day.

WHO At least 18 years of age with:

- high-risk TIA (defined as an ABCD² score ≥ 4)

or

- minor ischemic stroke (NIH Stroke Scale ≤ 3)

who can be randomized and treated within 12 hours of symptom onset.

4,150 subjects will be randomized 1:1 (clopidogrel: placebo) and followed for 90 days from randomization.

HOW For more information go to:

<http://www.POINTtrial.org>

WHERE POINT is a partnership of the UCSF Department of Neurology Stroke Sciences Group (SSG), the Neurologic Emergencies Treatment Trials (NETT) Network and the National Institute of Neurological Disorders and Stroke (NINDS) Clinical Research Collaboration (CRC).

One hundred and fifty different medical centers in the United States are part of this study.

WHY POINT is an acute intervention trial that will provide data unique from prior and on-going long-term secondary prevention trials.

Inclusion Criteria

Neurologic deficit (based on history or exam) attributed to focal brain ischemia and EITHER:

- high risk TIA: Complete resolution of the deficit at the time of randomization AND ABCD² score ≥ 4

OR

- minor ischemic stroke: residual deficit with NIHSS ≤ 3 at the time of randomization .

Ability to randomize within 12 hours of symptom onset.

Head CT or MRI ruling out hemorrhage or other pathology, such as vascular malformation, tumor, or abscess, that could explain symptoms or contraindicate therapy.

Subject will be prescribed aspirin at a dose of 50-325 mg/day.

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1-866-94-POINT (1-866-947-6468)

Exclusion Criteria

Age <18 years

TIA symptoms limited to isolated numbness, isolated visual changes, or isolated dizziness/vertigo.

Planned thrombolysis or endovascular intervention for the index event.

Receipt of any intravenous or intra-arterial thrombolysis within 1 week prior to index event.

Gastrointestinal bleed or major surgery within 3 months prior to index event.

History of non-traumatic intracranial hemorrhage.

Known internal carotid artery stenosis >50% that could be responsible for symptoms.

Clear indication for anticoagulation (e.g., warfarin, heparin) anticipated during the study period (atrial fibrillation, mechanical heart valve, deep venous thrombosis, pulmonary embolism, antiphospholipid antibody syndrome, hypercoagulable state).

Qualifying ischemic event induced by angiography or surgery.

Severe non-cardiovascular comorbidity with life expectancy <3 months.

Contraindication to clopidogrel or aspirin:

- Known allergy
- Severe renal (serum creatinine >2 mg/dL) or hepatic insufficiency (prior or concurrent diagnosis, with INR>1.5, or any resultant complication, such as variceal bleeding, encephalopathy, or icterus)
- Hemostatic disorder or systemic bleeding within the last 7 days
- Current thrombocytopenia (platelet count <100 x10⁹/l) or neutropenia (<1 x10⁹/l)
- History of drug-induced hematologic or hepatic abnormalities

Anticipated requirement for long-term (>7 days) nonstudy antiplatelet drugs (eg, dipyridamole, clopidogrel, ticlopidine), or NSAIDs affecting platelet function (such as prior vascular stent or arthritis).

Not willing or able to discontinue prohibited concomitant medications.

Inability to swallow medications.

At risk for pregnancy: premenopausal or postmenopausal woman within 12 months of last menses without a negative pregnancy test or not committing to adequate birth control (e.g., oral contraceptive, two methods of barrier birth control, or abstinence).

Unavailability for follow-up.

Inability to provide informed consent.

Other neurological conditions that would complicate assessment of outcomes during follow-up.

Current participation in any other study of investigational therapy, or participation in such a study within the last 7 days.