

**PROTOCOL FOR USE OF INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR
FOR ACUTE ISCHEMIC STROKE
HARBORVIEW MEDICAL CENTER – UNIV. OF WASHINGTON MEDICAL CENTER**

Based on protocols from NINDS t-PA Stroke Study Group (NEJM 1995;33:1581-87),
AAN Practice Advisory (Neurology 1996;47:835-839) and
AHA Guidelines (Stroke 1996;27:1711-1718, Stroke. 2005;36:916).

INCLUSION CRITERIA

- Age 18 or greater (safety and efficacy for patients > 80 yoa is based only on observational data, tPA should be used with caution).
- Clinical diagnosis of ischemic stroke causing a measurable neurologic deficit with NIHSS ≥ 4
 - defined as impairment of language, motor function, cognition, gaze, vision, neglect or some combination of these problems; isolated severe aphasia may present with NIHSS < 4 and still be worthy for consideration for IV tPA treatment.
 - Ischemic stroke is defined as an event characterized by the sudden onset of an acute focal neurologic deficit presumed to be due to brain ischemia after CT **excludes** hemorrhage.
- Onset of symptoms of ischemic stroke within 3 hours of the time to initiation of treatment with intravenous tissue plasminogen activator (t-PA).

CAUTIONARY CRITERIA

(not absolute contraindications, usually imply overall poorer prognosis, may increase risk of early symptomatic hemorrhage, yet do not exclude the possibility of benefit from tPA therapy)

- Age > 80 yoa (use is based only on observational, phase IV data, this should be pointed out during consent of such cases).
- Severe stroke; including coma, severe obtundation, fixed eye deviation or complete hemiplegia, NIH Stroke Scale ≥ 20
- Evidence of early CT changes consistent with brain ischemia, such as loss of differentiation between gray and white matter, sulcal effacement, hypodensity or mass effect. Especially if > 1/3 of the MCA territory.
- Pregnancy; tPA has been given, with varying levels of success, risks to fetus and woman not clearly known, but may be considerable.

EXCLUSION CRITERIA

- CT scan with evidence of hemorrhage.
- Patient has minor stroke symptoms (NIHSS < 4) or has major symptoms that are rapidly improving by the time of initiating treatment with t-PA.
- History of a stroke, myocardial infarction or head trauma within the previous 90 days.
- Paralysis that might be due to a known active seizure disorder or a first seizure within the 6 hours immediately prior to initiating treatment with t-PA.
- Previous known intracranial hemorrhage, neoplasm, subarachnoid hemorrhage, arteriovenous malformation, or aneurysm.
- Clinical presentation suggestive of subarachnoid hemorrhage, even if initial CT scan is normal.
- Hypertension with systolic blood pressure > 185 mm Hg or diastolic blood pressure > 110 mm Hg on repeated measures prior to study entry unresponsive to intravenous antihypertensives to reduce blood pressure to within these limits.
- Presumed septic embolus.
- Surgery or biopsy of parenchymal organ within the previous 14 days.
- Trauma with internal injuries or ulcerative wounds within the previous 30 days.
- Any active bleeding or acute trauma (fracture) on examination
- Gastrointestinal or urinary tract hemorrhage in previous 21 days.
- Known hereditary or acquired hemorrhagic diathesis
 - PTT or PT greater than normal;
 - unsupported coagulation factor deficiency;
 - oral anticoagulant therapy with prolonged PT (>15 sec or INR > 1.7);
 - use of heparin in previous 48 hours with a prolonged PTT;
 - use of any experimental antithrombotic agent or participation in such a trial (unless randomization is emergently broken and patient identified as having been on placebo).
 - [Note: use of ASA up until time of CVA was not an exclusion per NIH protocol, the effect of prior use of ticlopidine or clopidogrel has not studied thus is not a clear exclusion]
- Parturition within the previous 30 days.

- Baseline lab values:
 - glucose < 50 or > 400;
 - platelets < 100,000;
 - Hct < 25.
- Arterial puncture or venous puncture at non-compressible site in the last 7 days.
- Other serious, advanced, or terminal illness.
- Any other condition that the physician feels would pose a significant hazard to the patient if t-PA therapy were initiated.

If the patient has all of the inclusion criteria and none of the exclusion criteria, he or she is eligible for treatment with t-PA. If so, obtain informed consent and sign orders.

DRUG ADMINISTRATION

Dosage Information: see standing orders.

OTHER TREATMENTS

Antithrombotic therapies

Other antithrombotic therapies, including anticoagulants and antiplatelet agents, must be avoided for 24 hours following the administration of t-PA.

Hypertension

The protocol suggested by the NINDS t-PA Stroke Study Group will be followed. See standing orders for details.

Intracranial Hemorrhage

If neurologic deterioration, new headache, acute hypertension, nausea, vomiting or some combination of these problems, initiate the algorithm for suspected intracranial hemorrhage.

Algorithm for Treatment of Suspected Intracranial Hemorrhage after tPA (first 24 hrs after tPA)

