ATACH-II Inclusion/Exclusion Criteria v.5

Inclusion Criteria

- Age 18 years or older.
- IV nicardipine can be initiated within *4.5 hours* of symptom onset.
- Patient can be randomized within *4.5 hours* of symptom onset.
- Clinical signs consistent with the diagnosis of stroke, including impairment of language, motor function, cognition, and/or gaze, vision, or neglect.
- Total GCS score (aggregate of verbal, eye, and motor response scores) of 5 or greater at time of ED arrival.
- INR Value < 1.5
- CT scan demonstrates intraparenchymal hematoma with manual hematoma volume measurement <60 cc.
- For subjects randomized prior to IV antihypertensive administration: SBP greater than 180 mmHg** prior to antihypertensive treatment (this includes pre-hospital treatment) AND WITHOUT spontaneous SBP reduction to below 180 mmHg at the time of randomization

  OR
- For subjects randomized after IV antihypertensive administration: SBP greater than 180 mmHg** prior to antihypertensive treatment (this includes pre-hospital treatment) AND WITHOUT SBP reduction to below 140 mmHg at the time of randomization.
- Informed consent obtained by subject, legally authorized representative, or next of kin.

** Note: Patients with SBP < 180 mmHg should be monitored for 4.5 hours from symptom onset as their SBP may rise to eligible levels before the eligibility window closes.

Exclusion Criteria

- ICH is due to previously known neoplasms, AVM, or aneurysms.
- Intracerebral hematoma considered to be related to trauma.
- ICH located in infratentorial regions such as pons or cerebellum.
- IVH associated with intraparenchymal hemorrhage and blood completely fills one lateral ventricle or more than half of both ventricles.
- Patient to receive immediate surgical evacuation.
- Current pregnancy, or parturition within previous 30 days, or active lactation.
- Use of dabigatran within the last 48 hours.
- A platelet count less than 50,000/mm3
- Known sensitivity to nicardipine.
- Pre-morbid disability requiring assistance in ambulation or activities of daily living.
- Subject's living will precludes aggressive ICU management.
- Subject is currently participating in another interventional clinical trial