

Assessments and Activities	Hours						Days			
	Screening	0 (Base- line, pretreat- ment) ¹	>0-≤6 Q1H	>6-≤24 Q6H	>24-≤72 Q12H	>24-≤72 Q24H	5	10	30 (Phone)	90 (Final Visit) or Early Termina- tion)
Time Window	NA	NA	±20 min	±1 hr ²	±3 hr ²	±4 hr ²	±1 day ²	±1 day	±5 days	±14 days
Informed Consent	X ³									
Inclusion/Exclusion Criteria	X									
Demographics	X									
Medical History	X									
Vitals	X		X ⁴		X	X	X			X
NIH Stroke Scale	X		X ⁴	X ⁴		X	X			X
Barthel Index and modified Rankin Scale	X (prestroke)						X		X	X
Physical Examination	X						X			X
Neurological Examination	X						X			X
12-Lead ECG	X						X			
Fibrinogen (local)	X									
Fibrinogen (central)		X	X ⁵	X ⁵	X					
Hct, Hgb (central)						X		X		
Hematology (central)		X					X			
Chemistry (central)		X					X			
Immungenicity (central)		X								X
Urinalysis (local)	X						X			
Urine Drug Screen (local)	X									
Urine Pregnancy (local)	X									
Noncontrast Head CT	X									
Follow-up Noncontrast Head MRI							X ⁶			
Prior and Concomitant Medications	X	X	X	X	X	X	X	X	X ⁷	X ⁸
AEs	From consent	X	X	X	X	X	X	X	X ⁷	X ⁸
Infuse Study Medication		X	X ⁹ 2 hr ⁹							

Footnotes to this table are on the next page.

¹ 0 time, the time the study drug infusion begins, is defined as 0 day / 0 hr (meaning that if study drug begins on Mon, day 5 will be on Sat).

² Fibrinogens nominally drawn at 3, 4, 5, and 6 hrs are ± 20 min. All blood sampling for fibrinogen should be as close as possible to the nominal draw times, but even more importantly, the actual draw times must be accurately recorded. The time window for the day 5 MRI will be ± 12 hr; other day 5 assessments have a ± 1 day window.

³ Informed consent must be obtained before conducting any of the screening procedures not normally conducted in the evaluation of acute, ischemic stroke.

⁴ While the subject should be examined frequently to detect worsening, with unscheduled VS and NIHSS completed if needed, scheduled VS CRF pages after baseline will be recorded at 1, 2, 3, 6, 12, 18, 24, 48, and 72 hours and 5 and 90 days; scheduled NIHSS CRF pages after baseline will be recorded at 3, 12, 24, 48, and 72 hours and 5 and 90 days. For VS 0-6 hr and 6-24 hr, temperature will be taken only at screening and 24 hr (as well as at 48 and 72 hr and day 5).

⁵ Fibrinogens will be drawn for determination at a central laboratory at baseline (pretreatment) and at 3, 4, 5, 6, 9, 12, 24, 36, 48, 60, and 72 hrs; see the first footnote for recording sampling times.

⁶ Whenever possible, this imaging study should be done at 5 days. An earlier CT/MRI might be added to evaluate the possibility of an intervening intracranial hemorrhage.

⁷ The 30-day assessment by phone is for AEs, SAEs, concomitant medications, BI, mRS, and survival status.

⁸ At 90 days, only SAEs (with their corresponding AEs and concomitant medications) will be recorded; non-serious AEs and concomitant medications not related to an SAE will not be recorded.

⁹ Subjects with pretreatment fibrinogen levels of 100-199 mg/dL will be infused for only 2 (instead of 3) hours.