

ISCHEMIC STROKE: DEVICE CLINICAL STUDY CHART

For an expanded chart, please see our January issue online at PracticalNeurology.com

Sponsor	Study	Products	Type of Study	Center(s)	Cohort Source	Phase	Randomization	Blinding	Primary Endpoints	Secondary Endpoints
Stryker Neurovascular	DAWN	Trevo Retriever	IDE Pivotal	Multicenter	Prospective	510(k)	Randomized	Blinded	Weighted modified mRS score, Lead Co-Primary Efficacy Outcome; Functional Independence (mRS 0-2), Nested Co-Primary Efficacy Outcome; Stroke-related mortality, Primary Safety Outcome	Good functional outcome; Early response; All cause mortality; Revascularization rates
University of Calgary	ESCAPE	Solitaire	Controlled, Interventional, Postmarket	Multicenter	Prospective		Randomized	Open-label	Rapid endovascular revascularization amongst radiologically selected (small core/proximal occlusion) patients with ischemic stroke results in improved outcome	Proportion of patients who achieve an NIHSS score 0-2; Proportion of patients who achieve a mRS 0-2; Proportion of patients who achieve a Barthel Index > 90
Neuroscience Trials Australia	EXTEND IA	Solitaire	Controlled, Interventional	Multicenter	Prospective		Randomized	Non-blinded	Reperfusion at 24 hours post stroke onset (CT or MR perfusion imaging); Favorable clinical response (NIHSS \geq 8 points or reaching 0-1) at 3 days post stroke onset	Reperfusion 24 hours post stroke w/o symptomatic intracerebral hemorrhage 24 hours post stroke; Recanalization at 24 hours post stroke (CT or MR)
Joseph Broderick	IMS III	Merci Retriever, MicroLysis, Penumbra System	Controlled, Interventional	Multicenter	Prospective		Randomized	Open-label	mRS score dichotomized to 0-2 vs greater than 2 (at 90 days post); Death due to any cause; Symptomatic intracranial hemorrhage within the first 30 hours post IV rt-PA	Incidence of Parenchymal Type II Hematomas; Asymptomatic Hemorrhage (within 30 hours post IV rt-PA); NIHSS score dichotomized 0-1 vs 2 or greater (90 days post)
Erasmus MC University Medical Center, Rotterdam	MR CLEAN	Any FDA or CE Mark cleared device	Controlled, Interventional, Postmarket	Multicenter	Prospective		Randomized	Open-label	The primary outcome is the score on the Modified Rankin Scale at 90 days	NIHSS within 48 hours or at discharge; Infarct size assessed by CT at 2 days (includes manual tracing of the infarct perimeter and semi-automated pixel thresholding)
University of California, Los Angeles	MR RESCUE	Merci Retriever, Penumbra System	Controlled, Interventional, Postmarket	Multicenter	Prospective		Randomized	Open-label	The Modified Rankin Scale Score	Symptomatic Hemorrhagic Transformation at day 7; 90 day mortality
Fundacio Privada Ictus Malaltia Vascular	REVASCAT	Solitaire	Controlled, Interventional, Postmarket	Multicenter	Prospective		Randomized	Open-label	Distribution (Intention to Treat) of mRS scores at 90 days (Shift Analysis)	Infarct volume evaluation at 24 hour and successful recanalization in Solitaire arm according to TIC1 class 2b or 3
Medtronic (Covidien)	SWIFT PRIME	Solitaire	IDE Pivotal	Multicenter	Prospective	510(k)	Randomized	Open-label	90 day global disability assessed via blinded evaluation of mRS	Death due to any cause at 90 days; Functional independence (mRS score \leq 2) at 90 days; Change in NIHSS score at 27 \pm 6 hr post randomization
Central Hospital, Nancy, France	THRACE	Merci, Penumbra, Catch, Solitaire	Controlled, Interventional, Postmarket	Multicenter	Prospective		Randomized	Open-label	Determine whether a combined approach IV + Mechanical Thrombectomy is superior to the reference treatment with IV thrombolysis in the 3 hours of onset of symptoms and NIHSS \geq 10	Determine the cost-effectiveness of IV-tPA + Mechanical Thrombectomy. Assumption is by improving clinical outcome and speed recovery allows for lower overall costs in 3 months and less than or neutral at 1 year

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An Overview of Contemporary Acute Ischemic Stroke Studies Using Mechanical Thrombectomy

We have included mechanical thrombectomy clinical studies for acute ischemic stroke that were multicenter, greater than 50 patients, and included presented data. This chart is not meant to be an exhaustive list of all stroke clinical studies, but rather a list of studies that have helped shape the stroke treatment landscape.

Sample Size	Controls	Statistical Treatment	Regulatory Status	Regulatory Body	Regions	Mechanism of Action	Time to Treat	Scales of Assessment	Location of Occlusion	Primary Endpoint Outcome Parameter	Published Data
206	Medical	Superiority	Pre-approval	FDA	North America, Asia Pac, Europe	Retriever	Within 6 - 24 hours TLSW	mRS, NIHSS, TICl	ICA, M1, MCA	Stroke clinical outcomes	Nogueira RG, Jadhav AP, Haussen DC, et al. Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct. N Engl J Med. 2017. doi:10.1056/NEJMoa1706442.
316	Medical	Equivalence	Post-market	HealthCanada, CE Mark	Europe, Asia Pac, North America	Retriever	≤ 12 hours	mRS, NIHSS	ICA, M1, M2, MCA	Recanalization	Goyal M, Menon BK, van Zwam WH, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet. 2016;387(10029):1723-31.
70	Medical	Equivalence	Post-market	CE Mark	Asia Pac	Retriever	≤ 6 hours	mRS, NIHSS	ICA, M1, M2	Reperfusion	Campbell BC, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. N Engl J Med. 2015;372:1009-18.
656	Medical	Equivalence	Post-market	FDA	North America	Aspiration, Retriever	≤ 3 hours	mRS, NIHSS	Basilar, ICA, M1	Recanalization	Broderick JP, Palesch YY, Demchuk AM, et al. Endovascular therapy after intravenous t-PA versus t-PA alone for stroke. N Engl J Med. 2013;368:893-903.
500	Medical	Superiority	Post-market	CE Mark	Europe	Aspiration, Retriever	≤ 6.5 hours	mRS, NIHSS	ICA, M1, M2	Stroke clinical outcomes	Berkhemer OA, Fransen PS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. N Engl J Med. 2015;372:11-20.
127	Medical	Superiority	Post-market	FDA	North America	Aspiration, Retriever	≤ 8 hours	mRS, NIHSS	M1, M2, MCA	Recanalization	Kidwell CS, Jahan R, Gornbein J, et al. A trial of imaging selection and endovascular treatment for ischemic stroke. N Engl J Med. 2013;368:914-23.
206	Medical	Equivalence	Post-market	CE Mark	Europe	Retriever	≤ 8 hours	mRS, NIHSS	ICA, M1, M2	Reperfusion	Goyal M, Menon BK, van Zwam WH, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet. 2016;387(10029):1723-31.
196	Medical	Equivalence	Pre-approval	FDA	North America, Europe	Retriever	≤ 6 hours	mRS, NIHSS	M1, M2, MCA, ICA	Reperfusion	Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. N Engl J Med. 2015;372:2285-95.
412	Medical	Superiority	Post-market	CE Mark	Europe	Aspiration, Retriever	≤ 4.5 hours	mRS, NIHSS	ICA, M1	Stroke clinical outcomes	Bracard S, Ducrocq X, Mas JL, et al. Mechanical thrombectomy after intravenous alteplase versus alteplase alone after stroke (THRACE): a randomised controlled trial. Lancet Neurol. 2016;15:1138-47.

Abbreviations: ICA, Internal carotid artery; MCA, Middle cerebral artery; M1, Middle cerebral artery – Segment 1; M2, Middle cerebral artery – Segment 2; mRS, modified Rankin Score; NIHSS, National Institutes of Health Stroke Scale; TICl, Thrombolysis in cerebral infarction