Randomized Trial of Hemostatic Therapy for 'Spot Sign' Positive Intracerebral Hemorrhage: Primary Results From the SPOTLIGHT/STOP-IT Study Collaboration

Purpose: To evaluate a potential emergency treatment for intracerebral hemorrhage: use of the CT 'spot sign' to ID patients at high risk for more bleeding and who may benefit from treatment with recombinant factor VIIa (rFVIIa).

Trial Design: parallel, investigator-initiated, multicenter (26 sites); non-anticoagulated, spot-positive ICH patients randomly assigned 1:1 to intravenous rFVIIa 80µg/kg or placebo within 6h of onset. N=142

Primary Endpoint: blinded measurement of 24-hour ICH volume

Trial Results - change from baseline	recombinant factor VIIa (baseline to 24 hours)	placebo	P value
Median ICH volume	16 to 22	20 to 29	0.9
Median total volume	24 to 26	25 to 31	0.9

Conclusions: Emergency CT angiography had prognostic value in acute intracerebral hemorrhage, but treatment with rFVIIa did not improve hematoma volume or outcomes.

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