

EMBOLISE: Embolization of the MMA with Onyx™ Liquid Embolic System in the Treatment of Subacute and Chronic Subdural Hematoma

RESULTS: In participants with symptomatic subacute or chronic subdural hematoma (SDH), the addition of middle meningeal artery (MMA) embolization with Onyx™ resulted in nearly a 3-fold reduction in hematoma recurrence/progression requiring re-operation compared to surgery alone.

PURPOSE: To assess both the safety and effectiveness of utilizing the Onyx™ Liquid Embolic System (LES) for embolization of the MMA in the treatment of symptomatic subacute or chronic SDH as an adjunct to conventional treatment.

TRIAL DESIGN: A multicenter, prospective, randomized, interventional controlled, open-label, adaptive trial (n=400).

	Onyx Embo +Surgery (Treatment) N=197	Surgery Only (Control) N=203	Relative Risk (95%CI)	P value
Primary Endpoint				
SDH recurrence/progression requiring surgical drainage through 90 days (ITT population)	4.1 % (1.8%, 7.8%)	11.3% (7.3%, 16.5%)	0.36 (0.11, 0.80)	0.0081
Secondary Endpoints				
Incidence of deterioration in neurologic function	11.9% (21/177) (7.5%, 17.6%)	9.8% (18/184) (5.9%, 15.0%)	2.08% (-4.76%, 8.92%)	0.0022

Key Takeaways: The use of MMA embolization is a promising additional approach to the surgical management of subacute or chronic SDH.