

aMAZE: Left Atrial Appendage Ligation with the LARIAT System Adjunctive to Pulmonary Vein Isolation for Persistent or Longstanding Persistent Atrial Fibrillation

Purpose: To evaluate the efficacy of LARIAT LAA ligation as an adjunct to PVAI in decreasing the 12-month rate of atrial arrhythmias (AA) following initial ablation with an acceptable safety profile in pts with persistent or longstanding persistent AF and failed AAD therapy.

Trial Design: Prospective, multicenter RCT (N=610, 53 sites). Bayesian Adaptive, Superiority Design. Control: PVAI alone. Treatment: LARIAT ≥ 30 days prior to PVAI.

Primary Endpoints: 1) Safety: 30-day post LARIAT serious adverse events (SAEs) compared to performance goal (PG) ≤10%; 2)

Effectiveness: Freedom from documented AA episodes > 30 sec at 12M post PVAI.

Technical Success Endpoint: Successful LARIAT placement for effective LAA ligation (≤1 ± 1mm diameter residual communication).

Summary of Results: The LARIAT System appears safe and effectively excludes the LAA but did not significantly reduce the rate of recurrent AA in all pts with persistent and longstanding persistent AF. Exploratory analysis suggested that adjunctive LARIAT ligation may provide improved rhythm control in a subset of pts with early persistent AF and larger LA volumes that require further study.

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	LARIAT + PVAI N=372	PVAI Only N=198	Difference (%) Posterior Probability [95%Bayesian CI]
Primary Endpoints			
Safety (30D SAE rate)	3.4%		<10% PG; Posterior probability = 1 (>0.957) 95% Bayesian CI: (2.0, 5.0)
Effectiveness: Freedom from AA at 12M post PVAI	64.3%	59.9%	4.3% difference; Posterior probability = 0.835 (< 0.977) 95% Bayesian CI: (-4.2,13.2)
Technical Success (Residual communication w/ LA at 12 months post PVAI)			
0 mm	84%	≤ 3mm	93%
≤ 1±1 mm	85%	≤ 5 mm	99%
Exploratory Subset Analyses			
<ul style="list-style-type: none"> Freedom from AA in Early Persistent AF (79% of overall population): 66% with LARIAT + PVAI compared to 58.5%; difference of 7.5%; p-value 0.084 [95% Bayesian CI: -0.022, 0.174]; posterior probability = 0.931 Freedom from AA in Early Persistent AF and large LA volume (>133 cm³): 65.8% with LARIAT + PVAI compared to 53.4%; difference of 12.4%; p-value = 0.093 [95% Bayesian CI: -0.021, 0.263]; posterior probability = 0.952 			

Results reflect the data available at the time of presentation