

# Randomized trials of PFO closure and meta-analysis

Trial →	CLOSURE I	PC	RESPECT 2013	RESPECT 2017	REDUCE	CLOSE	DEFENSE-PRO
<b>Geography</b>	US/Can	Europe	Us/Can	US/Can	Scand/US	French	Korean
<b>Patients</b>	909	414	980	980	664	473	120
<b>Age</b>	≤60	<60	18-60	18-60	18-59	16-60	34-66
<b>N (PFO/med)</b>	447/462	204/210	499/481	499/481	441/223	238/233	60/60
<b>Device</b>	STARFlex	Amplatzer	Amplatzer	Amplatzer	Gore septal occluder	Various allowed (>50% were Amplatzer)	Amplatzer
<b>MMx (PFO/Med)</b>	DAPT 6mo → ASA/ASA or Warf or both	ASA 6mo/AC 6mo → ASA (or per MD)	DAPT1mo → ASA5mo/ASA, warf, Plav, DAPT, Eggenox DAPT not allowed after 2006	DAPT1mo → ASA5mo/ASA, warf, Plav, DAPT, Eggenox DAPT not allowed after 2006	AP/AP 2:1 ASA/aggren/ Plavix	AP/AP/AC 1:1:1	DAPT or AC or Monotherapy AP
<b>PFO dx modality</b>	TTE bubble	TEE bubble and/or color doppler	TEE bubble	TEE bubble	TEE bubble	TTE/TEE PFO+ASA >10mm on TTE, OR PFO + large shunt >30 microbubbles on TTE/TEE	TEE bubble High risk PFO ASA ≥ 15 mm or hypermobility ≥ 10 mm or size ≥ 2 mm

<b>Shunt size</b>	Any	Any	Any	Any	Any	ASA or large	Any
<b>CVA def</b>	Cryptogenic ischemic stroke or TIA <6 mo	Ischemic stroke, TIA or peripheral embolism	Cryptogenic ischemic stroke <9mo	Cryptogenic ischemic stroke <9mo	Cryptogenic embolic appearing ischemic stroke or TIA ,6 mo (sx > 24h)	Cryptogenic stroke-imaging proven <6mo + mRS ≤3	Cryptogenic stroke within 6 months
<b>Prim EP</b>	Stroke or TIA at 2y +30d mortality and neurologic mortality beyond 30d	Death, nonfatal stroke, TIA, or peripheral embolism	Recurrent nonfatal ischemic stroke, fatal ischemic stroke, or early death after randomization	Recurrent ischemic stroke Recurrent crypto stroke ASCOD Recurrent crypto stroke TOAST	1. Freedom from stroke 2y 2. New brain infarct (clinical or silent on imaging) through 2y	Recurrent fatal or nonfatal stroke (clinically only deficit >24h OR clinical deficit + MRI/CT evidence)	.42 RR for recurrent stroke NS for TIA and mortality
<b>Mean f/u</b>	2y	4.1y	2.6y	5.9y	3.2y	5.3y	2.8y
<b>Diagnosis of cryptogenic stroke</b>	Not reported	Standard workup including Holter at baseline	Standard workup, Holter not required	Standard workup, Holter not required	Standard workup, Holter not required	Standard workup including a negative 24-h Holter monitoring	Standard workup including holter/prolonged cardiac monitor