

# Early Feasibility Study (EFS) Evaluating Percutaneous Repair of the Atrial Septum With a Novel PFO Occluder: The PROTEA-PFO Study

NCT07172464

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Recross Cardio, Inc.
Enrollment	15 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Patient must be e 18 and d 65 years of age
  - Diagnosis of PFO, defined as visualization of microbubbles per TEE in the left atrium within three cardiac cycles from the right atrial opacification demonstrating right-to-left shunting at rest and/or during Valsalva release.
  - Ischemic stroke, defined as acute focal neurological deficit, presumed to be due to focal ischemia and confirmed by MRI or CT to have a neuroanatomically relevant cerebral infarct.
  - Modified Rankin score (mRS) d 3.
  - Appropriate PFO anatomy for implantation of the investigational device as evaluated and determined by independent committee.
- ... and 2 more (see full listing online)

### Exclusion (28)

- Other identifiable causes of stroke, including but not limited to aortic arch plaques (protruding  $\gt 4$  mm into the lumen), large artery atherosclerotic disease proximal to the territory of the index stroke, an established cardioembolic source, small-vessel occlusive disease, or arterial dissection, presence of left atrial appendage thrombus.
  - Other arteriopathy of the intracranial or extracranial vessels with  $\gt 50\%$  stenosis proximal to the territory of the index stroke.
  - Intracardiac thrombus or tumor.
  - Myocardial Infarction (MI) or unstable angina within the previous 180 days.
  - Life expectancy  $\lt 2$  years.
- ... and 23 more (see full listing online)

## Locations (5 total)

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UCLA, Los Angeles, California, United States  
The Cardiac and Vascular Institute, Gainesville, Florida, United States  
Tufts Medical Center, Boston, Massachusetts, United States  
... and 2 more locations

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<https://clinicaltrials.gov/study/NCT07172464>

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