

# Cerebral Microembolization Associated With PFO Closure

NCT06347276

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Status	RECRUITING
Sponsor	China National Center for Cardiovascular Diseases
Enrollment	800 participants

## Key Eligibility Criteria

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### Inclusion (3)

- PFO group
- \) age 18 to 65 years; 2) documented PFO with medium-to-large shunts (e 20 microbubbles by c-TCD at rest or during the Valsalva maneuver); 3) history of embolic stroke (based on brain magnetic resonance imaging within 24 hours after symptom onset) or TIA within 6 months without other identifiable causes; 4) history of migraine for more than one year without other identifiable causes; 5) asymptomatic group: incidental finding of PFO in asymptomatic individuals, and presence of high-risk activities and/or anatomical features related to PFO (high-risk activities were defined as those in which the Valsalva maneuver was performed frequently or those that increased the risk of venous gas formation; and high-risk anatomical features included atrial septal aneurysm and/or curtain pattern on c-TCD).
- \) age 18 to 65 years; 2) secundum ASD size 10 to 20 mm, with sufficient surrounding rims, except the aortic rim; 3) right heart catheterization: resting SPAP  $\leq$  50 mm Hg, Qp/Qs  $\geq$  1.5 and PVR  $\leq$  5 WU.

### Exclusion (3)

- \) presence of any known vascular risk factor, including hypertension, hypercholesterolemia, diabetes mellitus, atrial fibrillation, smoking and obesity; 2) history of embolic stroke or TIA within the past one month; 3) history of deep vein thrombosis or pulmonary embolism; 4) presence of coronary artery disease and carotid artery lesions; 5) presence of coexistent cardiovascular structural malformations or diseases; 6) allergy to contrast medium; 7) refusal to participate.
- ASD group
- \) presence of any known vascular risk factor, including hypertension, hypercholesterolemia, diabetes mellitus, atrial fibrillation, smoking and obesity; 2) associated with other cardiac abnormalities or diseases; 3) resting SPAP  $\geq$  50 mm Hg and resting PVR  $\geq$  5 Wood units; 4) primum or sinus venosus type ASD; 5) presence of intracardiac thrombi, permanent contraindications to platelet therapy, and allergic reaction to nickel.

## Locations (1 total)

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Chaowu Yan, Beijing, Beijing Municipality, China