COHEREX-EU:A Multi-Center Study to Evaluate the Safety and Efficacy of the Coherex FlatStent Patent Foramen Ovale(PFO) Closure System

ACTRN12607000623493

Status	RECRUITING
Sponsor	Coherex Medical Inc.
Enrollment	50 participants

Plain Language Summary

This study is testing a new device called the Coherex FlatStent, which is used to close a small hole in the heart called a Patent Foramen Ovale (PFO). A PFO is a flap-like opening between the two upper chambers of the heart that normally closes shortly after birth, but in some people it stays open. It can sometimes allow blood clots to pass through, increasing the risk of stroke. The device is inserted through a vein without open-heart surgery. The study involves the first 50 patients to receive this device and will track safety and effectiveness.

You may be eligible if:
- You are between 18 and 65 years of age
- You have been diagnosed with a Patent Foramen Ovale (PFO)
- Your doctor has recommended closure of the PFO using a non-surgical (percutaneous) approach

You may NOT be eligible if:
- You have allergies to aspirin, clopidogrel, nickel, or other stent materials
- You had a major stroke in the last 2 months or a minor stroke in the last 2 weeks
- You have a blood clot inside the heart
- You may be pregnant
- You have an active infection or sepsis
- You have other significant structural heart disease or coronary artery disease
- You have a known sustained irregular heart rhythm (arrhythmia)

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

- Patients between 18 and 65 years of age with a Patent Foramen Ovale and a clinical indication for closure of the PFO by percutaneous methods.

Exclusion (14)

- Candidates will be excluded from the study if ANY of the following conditions apply:
- Patients with a contraindication and/or allergy to aspirin, Clopidrogel, Nitinol, Dacron polyurethane, nickel, stainless steel or other stent materials.
- Patients allergic to intravenous (IV) contrast and any combination of drug allergies that would preclude adequate antiplatelet or alternative anticoagulant therapy.
- Patients who have extensive congenital cardiac anomalies, which can only be adequately repaired by cardiac surgery.
- Patients who have had a major stroke within the past 2 months or a minor stroke within the past two weeks.

... and 9 more (see full listing online)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12607000623493

Locations (2 total)

Germany
New Zealand