Coherex-PFO-Sleep Hypoxia: A multi-center study to determine the response to closure of patent foramen ovale (PFO) with the Coherex FlatStentTM EF PFO Closure System (EF is part of the trade mark name and stands for Enhanced Foam) in patients diagnosed with PFO and significant oxygen desaturation in obstructive sleep apnea (OSA)

ACTRN12610000184077

Status	RECRUITING
Sponsor	Coherex Medical Inc.
Enrollment	50 participants

Plain Language Summary

This study is testing whether closing a small hole in the heart called a patent foramen ovale (PFO) — a natural opening between the upper chambers of the heart that normally closes after birth but sometimes stays open — can improve oxygen levels during sleep in people with obstructive sleep apnoea (OSA). OSA causes people to repeatedly stop breathing during sleep, and a PFO may worsen the drop in oxygen levels that occurs during these episodes.

You may be eligible if:
- You are between 18 and 65 years old
- You have a confirmed diagnosis of obstructive sleep apnoea with significant oxygen drops during sleep
- A special ultrasound test (transcranial Doppler) has shown you have a Grade IV or V right-to-left shunt through a PFO
- You have a PFO that can be closed with the specific device used in this study

You may NOT be eligible if:
- You require long-term blood thinners or have a clotting disorder
- You are allergic to aspirin, clopidogrel, or materials in the device (such as nickel or Dacron)
- Your BMI is over 40
- You have other significant heart disease, coronary artery disease, or atrial fibrillation
- You have chronic liver or kidney disease
- You are pregnant or wish to become pregnant during the study
- You have had a major stroke in the past 2 months or a minor stroke in the past 2 weeks
- You have uncontrolled high blood pressure, insulin-dependent diabetes, or significant lung disease

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

Key Eligibility Criteria

Inclusion (1)

• Diagnosis of OSA and a polysomnogram within the past year that demonstrated an apnea index > 20 seconds (AI20) of greater than 5 and an oxygen desaturation index > 6% (ODI6) of greater than 5 associated with apnic events. Patients willing to under go transcranial doppler (TCD) and demonstrates a Grade IV or Grade V right-to-left shunt. Patients must demonstrate a PFO amenable to transcatheter closure with the Coherex FlatStentTM EF PFO Closure System.

Exclusion (1)

• Candidates will be excluded from the study if ANY of the following conditions apply: 1. Long-term requirement for anti-platelet therapy, anticoagulation, or coagulopathy. 2. Contraindication and/or allergy to aspirin, clopidogrel, Nitinol, Dacron, polyurethane, nickel, stainless steel or other stent materials. 3. Concurrent enrollment in another clinical study. 4. Body mass index > 40. 5.

Botox treatment within the past 90 days. 6. Other known structural heart disease, coronary artery disease, or atrial fibrillation. 7. Chronic liver disease, kidney disease, or organ failure. 8. Auto-immune disease. 9. Psychiatric illness, which in the investigator's opinion, will interfere with completion of the study. 10. Degenerative neurologic disorders. 11. Any known active bacterial infection. 12. Malignancy or other illness with a life expectancy less than two years. 13. Pregnancy or desire to become pregnant during course of study. 14. Right-to-left shunt besides PFO detected prior to enrollment. 15.Uncontrolled hypertension defined as blood pressure greater than140/90 mmHg. 16. Immunosuppressive therapy. 17.Diabetes requiring insulin or blood glucose greater than 200 mg/deciliter on oral diabetic medications. 18. Concomitant pulmonary disorder (chronic obstructive pulmonary disorder [COPD], asthma, etc.) requiring treatment. 19. Any medical disorder that would interfere with study completion. 20. Known severe pulmonary hypertension (requiring medication). 21.Patients who have had a major stroke within the past two months or a minor stroke within the past two weeks (see National Institutes of Health (NIH) Stroke Scale). 22. Patients who require a transseptal puncture to access the left atrium. 23. Patients with known sustained arrhythmia.

Locations (3 total)

Auckland, New Zealand
Frankfurt, Germany
Paris, France