RESPONDER-HF

A confirmatory trial of the Corvia® Atrial Shunt for heart failure patients with an EF ≥40%

WHAT IS RESPONDER-HF?

A randomized, double-blinded, sham-controlled trial to confirm the clinical efficacy of the Corvia Atrial Shunt in HF patients with an LVEF ≥40%, elevated left sided filling pressures, and who remain symptomatic despite Guideline Directed Medical Therapy (GDMT).

STUDY RATIONALE

To confirm the findings from REDUCE LAP-HF II, the largest randomized controlled trial of a device-based therapy for HFpEF. Results from REDUCE LAP-HF II showed that in the large responder population, representing 50% of patients, treatment with the Corvia Atrial Shunt resulted in a 45% reduction in HF events (p=0.034) and a 55% greater improvement in quality of life compared to sham control at one year (p=0.027).[1]

TRIAL DESIGN

The study closely mirrors REDUCE LAP-HF II, with new exclusions for patients with worse right ventricular function resulting from latent pulmonary vascular disease (identified by elevated exercise PVR) or associated with cardiac rhythm devices.

STUDY POPULATION

N = 260 randomized

- Age ≥40
- Preserved RV function
- Exercise PCWP (≥25 mmHg) with left-to-right gradient (≥5 mmHg)
- Exercise PVR <1.75 WU
- No cardiac rhythm device

CORVIA ATRIAL SHUNT

N = 130

SHAM CONTROL

N = 130

PRIMARY COMPOSITE ENDPOINT

- Rate of total HF events (first and recurrent) up to 24 months, analyzed when last randomized patient reaches 12 months
- KCCQ (OSS) change from baseline to 12 months

MAJOR SECONDARY ENDPOINT

- Cardiovascular mortality through 12 months

WHO SHOULD BE CONSIDERED?

Patients age 40+ who have symptomatic HF or unexplained exertional dyspnea.

- Left ventricular ejection fraction ≥40%
- New York Heart Association class II–IV
- Relatively normal right ventricular function
- Elevated left-sided filling pressures
- Absence of significant valve disease
- Absence of a cardiac rhythm device

[1] Borlaug, BA et al.. *Circulation*. 2022;10.1161.

Study sponsored by Corvia Medical. clinicaltrials.gov identification #NCT05425459

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Consider giving your HFpEF patients a new opportunity to find relief.

Learn more

CAUTION: Investigational Device.
Limited by United States law to investigational use.

The **Corvia Atrial Shunt System** is an **Investigational Device**, exclusively for use in a Clinical Investigation.