corvia®

REDUCE LAP-HF II

Corvia® Atrial Shunt in heart failure with preserved or mildly reduced ejection fraction

2-YEAR RESPONDER GROUP HIGHLIGHTS

50%
Reduction in HF event rate compared to sham control

46%
Greater improvement in KCCQ compared to sham control

98%
Patency*

CONCLUSION

The Corvia Atrial Shunt improved quality of life and reduced heart failure (HF) symptoms and events through 2 years without a safety signal in appropriately selected HF patients with an ejection fraction (EF) ≥40%.[1]

BACKGROUND

REDUCE LAP-HF II is the world's first phase III randomized trial for atrial shunting in HF. It defined the optimal patient population for atrial shunt therapy (the "responder" population) and demonstrated the Corvia Atrial Shunt was safe, significantly reduced HF events, and improved quality of life in the responder population compared to sham control at one year.[2]

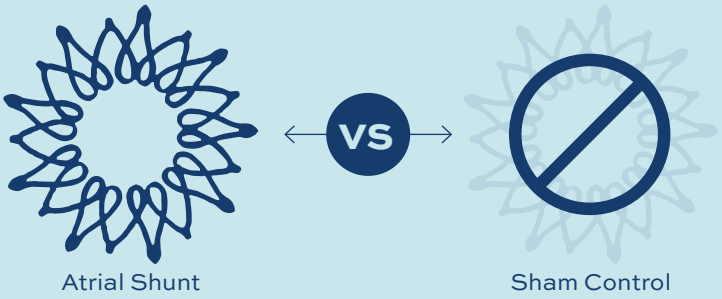
STUDY OBJECTIVES

Evaluate the longer-term (2-year) clinical efficacy and safety of the Corvia Atrial Shunt to improve quality of life and reduce HF-related symptoms and events in the previously identified responder population.[3]

STUDY POPULATION

Randomized, double-blind, placebo-controlled

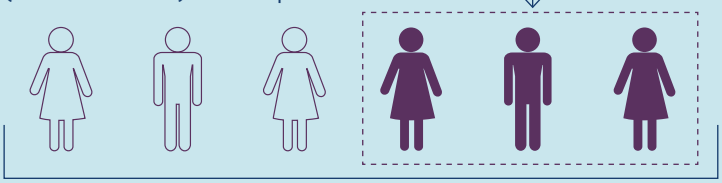
621 patients



PATIENTS INCLUDED: ≥40 years with symptomatic HF and EF ≥40% with elevated exercise PCWP (≥25 mm Hg) and left-to-right gradient (≥5 mm Hg)

RESPONDER COHORT Identified (n=313)

Patients without significant pulmonary vascular disease (PVR<1.74 WU) and no pacemaker



Overall Population

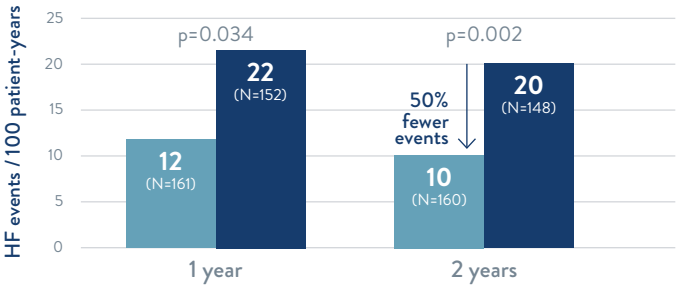
Follow-Up Blinding Maintained Through 2 Years

* Based on echo studies evaluable for shunt flow by the echo core lab

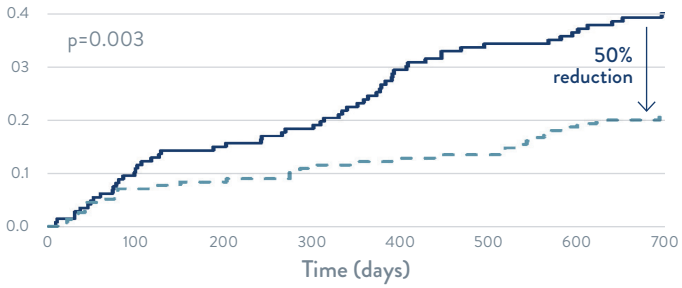
Responder Population Outcomes at 2 Years[1] (n=313)

HEART FAILURE EVENTS

Heart Failure Event Rate



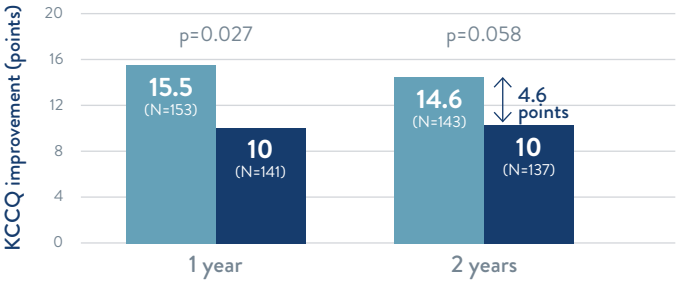
Mean Cumulative Heart Failure Events



Shunt therapy led to a 50% reduction in the rate of HF events

QUALITY OF LIFE

KCCQ-OSS Change from Baseline



Shunt patients sustained improved health status with 46% greater improvement (+4.6 points) in KCCQ

Corvia Atrial Shunt Sham Control

Learn More

Prof. Finn Gustafsson and Prof. Maja Cikes share their thoughts on the 2-year data from REDUCE LAP-HF II

KEY SAFETY OUTCOMES

Events in Responders through 2 years	Corvia Atrial Shunt (N=161)	Sham control (N=152)	p-value
Cardiovascular mortality	3/160 (1.9%)	2/148 (1.4%)	0.72
Non-fatal ischemic stroke	3/160 (1.9%)	0/148 (0.0%)	--
New or worsening kidney dysfunction	14/160 (8.8%)	22/148 (14.9%)	0.10
Major adverse cardiac events	6/160 (3.8%)	4/148 (2.7%)	0.61
Thrombo-embolic complications	1/160 (0.6%)	1/148 (0.7%)	0.96
≥30% Decrease in TAPSE	5/160 (3.1%)	4/148 (2.7%)	0.83

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1. Gustafsson, F, Petrie, M, Komtebedde, J et al. Two-Year Outcomes of an Atrial Shunt Device in HFpEF/HFmrEF: Results from REDUCE LAP-HF II. *J Am Coll Cardiol HF* (under review).
2. Borlaug, BA, Blair, J, Bergmann, MW et al. Latent Pulmonary Vascular Disease May Alter the Response to Therapeutic Atrial Shunt Device in Heart Failure. *Circulation.* 2022;10.1161/CIRCULATIONAHA.122.059486.
3. Berry, N, Mauri, L, Feldman, T et al. Transcatheter InterAtrial Shunt Device for the treatment of heart failure: Rationale and design of the pivotal randomized trial to REDUCE Elevated Left Atrial Pressure in Patients with Heart Failure II (REDUCE LAP-HF II). *Am Heart J*. 2020;226:222-31.

CAUTION: Investigational Device. Limited by United States law to investigational use. To be used by qualified investigators only. For use in a pre-market clinical investigation only.