Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation

COAPT

COAPT is a landmark trial to further study the MitraClip device in symptomatic FMR patients with heart failure. The study will generate important clinical and economic data to support guidelines. COAPT is the first randomized controlled clinical trial to compare non-surgical (medical) standard of care treatment to a percutaneous intervention to reduce MR.

Key Inclusion Criteria

- Functional MR ≥3+ due to cardiomypathy of either ischemic or non-ischemic etiology
- Qualifying TTE must be obtained after subject has been stabilized on optimal medical therapy
- Symptomatic (NYHA class II, III or ambulatory IV)
- Local Site Heart Team (CT surgeon and HF specialist investigating) and the Central Eligibility Committee concur that surgery will not be offered as a treatment option and that medical therapy is the intended therapy for the subject, even if the subject is randomized to the Control
- The subject has had at least 1 HF hospitalization in the 12 months prior to enrollment and/or a corrected BNP ≥300 pg/ml or nT-proBNP ≥1500 pg/ml measured within 90 days prior to registration
- Subject has been adequately treated per applicable standards for CAD, LV dysfunction, MR or HF (CHF, revascularization, and/or CMC)

Key Exclusion Criteria

- Mitr valve anatomic criteria
- Objective
- Randomize 1:1
- Mitral valve surgery
- Standard of Care
- Control Group

Primary Safety (1 year)

- Recurrent heart failure hospitalizations

Secondary Safety

- Recurrent heart failure hospitalizations
- Change in LVEDV at 12 months
- Change in 6MWD at 12 months
- MR severity at 12 months

Secondary Effectiveness

- Change in NYHA Functional Class I/II at 12 months
- Reduction to NYHA Functional Class I/II at 12 months
- Hierarchical composite of death and recurrent HF hospitalization (analyzed when the last subject completes 12 months of follow-up)
- Recurrent hospitalizations - all-causes (analyzed when the last subject completes 12 months of follow-up)

Secondary Efficacy

- Composite of death (all-causes), stroke, MI, non-elective CV surgery for device related complications in Device group at 30 days

Status

Enrollment as of August 18, 2014:
- Screened: 477
- Randomized: 113
- Follows:

For more information, please contact: info@COAPTtrial.com
http://www.COAPTtrial.com

Trial Design

430 patients enrolled at up to 79 US sites

Control Group

Randomize 1:1

MitraClip N=215

Clinical and TTE follow-up

48 weeks post-implant

Clinical N=215

Follow-up

1, 12, 24, 48, 60 months

Clinical Outcomes

Mortality

Composite of death (all-cause), stroke, MI, non-elective CV surgery for device related complications

Hospitalization

Hospitalization for recurrent HF at 12 months

Primary and Secondary endpoints

Echocardiography

Echocardiographic evidence of moderate or severe right ventricular dysfunction

Tricuspid valve disease or atrial valve disease requiring surgery

ACC/AHA Stage D heart failure

Institutional Review Board Approval

Primary and Secondary endpoints

Study Organization

Abbott Vascular Inc.

Evalve, Inc., a subsidiary of Abbott Vascular Inc.

Cardiovascular Research Foundation (New York, NY)

Cardiovascular Research Foundation (New York, NY)

Cardiothoracic Surgeon with experience in mitral valve surgery

Cardiothoracic Surgeons

Heart Failure Specialists

Echocardiography

Study Design

COAPT Trial: Overview

MitraClip

Control Group

Randomize 1:1

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