Dafodil-1 Study

A clinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve

Study Design

- Prospective, multi-center, single-arm study
- 60 subjects enrolled at 7 sites across India

CTRI No.	**CTRI/2017/07/009008**
Study Objective	To evaluate the clinical safety and performance of the Dafodil™ Pericardial Bioprosthesis by establishing associated adverse event rates, clinical status as indicated by New York Heart Association (NYHA) functional classification, hemodynamic performance of the prosthesis and hematology analysis
Safety Endpoints	• MACE • Cardiovascular Mortality • Stroke and Transient Ischemic Attack (TIA) • Major Bleeding • Minor Bleeding • Acute kidney injury (AKIN classification) • Valve thrombosis • Structural valve deterioration • Prosthetic valve endocarditis • Major paravalvular leak • Conduction disturbances and arrhythmias • Non-structural valve dysfunction • Mitral valve apparatus damage or dysfunction • Aortic valve apparatus damage or dysfunction • Explant • Hemolysis
Performance Endpoints	• NYHA Class • Quality of life (measured by SF-12 questionnaire) • Hemodynamic performance ECHO data analysed by CBCC Global Research LLP, India • Device Success
Clinical Sites	7 sites across India
Sample Size	60 patients (Aortic:30 patients; Mitral: 30 patients)
Follow-Up	1, 6 months and annually thereafter till 5 years

Study Duration	Study start date: July 2017 Estimated study completion: July 2023

Reference

1. Clinical Trial Registry- India (CTRI): CTRI/2017/07/009008 http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=18377&EncHid=&userName=CTRI/2017/07/009008