Clinical Trial Details (PDF Generation Date :- Sun, 26 Jun 2022 22:11:45 GMT)

CTRI Number	CTRI/2010/091/000415 [Registered on: 11/05/2010] -
Last Modified On	05/02/2016
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Ayurveda
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	A clinical trial to study the effect of Arjuna in heart failure patients
Scientific Title of Study	Double-blind, randomised placebo controlled clinical trial to study the add-on efficacy of a standardised preparation of the water extract of Terminalia arjuna in patients with Left Ventricular Dysfunction, already receiving standard drug regimen

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Affiliation	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Department of Biotechnology, Government of India

Primary Sponsor

Primary Sponsor Details	
Name	Department of Biotechnology Government of India
Address	CGO Complex, Lodhi Road, New Delhi
Type of Sponsor	Government funding agency

Details of Secondary Sponsor

Name	Address
Department of Pharmacology AIIMS	

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
S Seth	All India Institute of Medical Sciences	Ansari Nagar,-110029 New Delhi DELHI	01126584970 01126588641 sdrsandeepseth@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institute Ethics Committee, AIIMS	Approved	No Date Specified	Not Available

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
	Patients with chronic stable heart failure (Class II with EF<40%)

Intervention / Comparator Agent

Type	Name	Details
Intervention	Standardised water extract of the bark powder of Terminalia arjuna	750mg BID for 12 weeks
Comparator Agent	PLACEBO	One Capsule BID for 12 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	
Age To	
Gender	
Details	Patients (18 years and above) with chronic stable heart failure (stable for three months) with a left ventricular ejection fraction of less than 40 %.

Exclusion Criteria

Exclusion Criteria	
Details	1. History of MI or unstable angina within the last 4 weeks. 2. Revascularisation procedures (CABG OR PTCA) done in the past 3 months. 3. Planned for revascularisation in the next three months. 4. Recent stroke or TIA. 5. Uncontrolled hypertension (should be controlled before inclusion) 6. Pregnancy. 7. Other major organ dysfunction. 8. Primary valvular heart disease. 9. Evidence suggestive of ongoing or resolving carditis. 10. Evidence of coarctation of aorta or aortoarteritis. 11. Hypothyroidism

Method of Generating Random Sequence

Computer generated randomization

Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Improvement in left ventricular function with reduction in left ventricular dimensions.	12 weeks

Secondary Outcome

Outcome	Timepoints
1. Clinical improvement in the form of symptom class and distance covered in the 6 minute walk test. 2. Improvement in the Kansas City Cardiomyopathy Questionnaire to assess improvement in quality of life. 3. Reduction in plasma markers of congestive heart failure including serum cytokines, BNP and hsCRP. 4. Effects on endogenous antioxidants.	12 weeks

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=** **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	Phase 2
Date of First Enrollment (India)	No Date Specified
Date of First Enrollment (Global)	12/06/2010
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	In Indian Traditional Medicine (Ayurveda), the stem bark of the tree Terminalia arjuna (arjuna) has been known to be effective in different cardiac ailments. Various animal studies have demonstrated its significant cardiotonic, antioxidant and hypolipidemic activities. A number of small clinical studies have also suggested its activity in ischemic heart disease and heart failure. A randomised, double blind, placebo-controlled trial has been designed to evaluate the efficacy of a standardised water extract of the stem bark of T. arjuna in the treatment of left ventricular dysfunction. The objectives of the proposal include i) evaluation of its efficacy on cardiac functions in patients of heart failure, along with ii) changes in its major prognostic biomarkers , like plasma brain natriuretic peptide (BNP), tissue necrotic factor-alpha, interleukin-6 and iii) serum antioxidants. The study will be carried out in 100 patients over 12 weeks, with monitoring of different cardiac, hepatic and renal functions at predetermined intervals. The proposed study will provide significant scientific credence to the widely claimed therapeutic benefits of Terminalia arjuna.