



Clinical Trial Details (PDF Generation Date :- Fri, 22 Nov 2024 02:38:59 GMT)

<b>CTRI Number</b>	CTRI/2024/03/064384 [Registered on: 19/03/2024] - <b>Trial Registered Prospectively</b>																	
<b>Last Modified On</b>	24/10/2024																	
<b>Post Graduate Thesis</b>	No																	
<b>Type of Trial</b>	Interventional																	
<b>Type of Study</b>	Process of Care Changes																	
<b>Study Design</b>	Cluster Randomized Trial																	
<b>Public Title of Study</b>	Developing a protocol for managing pregnant women with heart disease in India, and evaluating the efficacy of the new protocol in improving pregnancy outcome compared to standard care.																	
<b>Scientific Title of Study</b>	DevelopmeNt, implementation and evaluation of Protocolized cArdio-obstetric Care in improving maternal cardiac, obstetric and fetal outcomes of Pregnant Women with Heart Diseases in India																	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>																
	NIL	NIL																
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<table border="1"> <thead> <tr> <th colspan="2">Details of Principal Investigator</th> </tr> </thead> <tbody> <tr> <td><b>Name</b></td> <td>Dr G Justin Paul</td> </tr> <tr> <td><b>Designation</b></td> <td>Professor of Cardiology</td> </tr> <tr> <td><b>Affiliation</b></td> <td>Madras Medical College</td> </tr> <tr> <td><b>Address</b></td> <td>Second floor, Institute of Cardiology, Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai Chennai TAMIL NADU 600003 India</td> </tr> <tr> <td><b>Phone</b></td> <td>9840071558</td> </tr> <tr> <td><b>Fax</b></td> <td></td> </tr> <tr> <td><b>Email</b></td> <td>drjpheart@gmail.com</td> </tr> </tbody> </table>		Details of Principal Investigator		<b>Name</b>	Dr G Justin Paul	<b>Designation</b>	Professor of Cardiology	<b>Affiliation</b>	Madras Medical College	<b>Address</b>	Second floor, Institute of Cardiology, Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai Chennai TAMIL NADU 600003 India	<b>Phone</b>	9840071558	<b>Fax</b>		<b>Email</b>	drjpheart@gmail.com
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>																												
	> Indian Council of Medical Research, Ansari Nagar, New Delhi-110029																												
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>																												
<b>Name</b>	Indian Council of Medical Research																												
<b>Address</b>	Ansari Nagar, New Delhi-110029																												
<b>Type of Sponsor</b>	Government funding agency																												
<b>Details of Secondary Sponsor</b>	<table border="1"> <tr> <th>Name</th><th>Address</th></tr> <tr> <td>NIL</td><td>NIL</td></tr> </table>	Name	Address	NIL	NIL																								
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<b>Sites of Study</b>	<table border="1"> <thead> <tr> <th>Name of Principal Investigator</th><th>Name of Site</th><th>Site Address</th><th>Phone/Fax/Email</th></tr> </thead> <tbody> <tr> <td>Dr Anish Keepanasseril</td><td>Jawaharlal Institute of Postgraduate Medical Education &amp; Research</td><td>Department of Gynaecology, JIPMER Campus Rd, Gorimedu, Dhanvantari Nagar, Puducherry, 605006 PONDICHERRY</td><td>8903307141 keepan_r@yahoo.com</td></tr> <tr> <td>Dr Surender Deora</td><td>All India Institute of Medical Sciences , Jodhpur</td><td>Room no:45, OPD BLOCK, 4TH FLOOR, C-BLOCK, Marudhar Industrial Area, 2nd Phase, M.I.A. 1st Phase, Basni, Basni, Jodhpur, Rajasthan 342005 Jodhpur RAJASTHAN</td><td>8003996715 deoras@aiimsjodhpur.edu.in</td></tr> <tr> <td>Dr Vatsla Dadhwal</td><td>All India Institute of Medical Sciences, Delhi</td><td>Room 714, Mother and Child Block, Ansari Nagar, New Delhi 110608 South West DELHI</td><td>9811015979 vatslad@gmail.com</td></tr> <tr> <td>Dr Arijit Kumar Ghosh</td><td>All India Institute of Medical Sciences, Nagpur</td><td>Room No: 140, OPD Block, MIHAN, Nagpur, Sumthana, Dahegaon, Maharashtra 441108 Nagpur MAHARASHTRA</td><td>8007658278 akumarg@aiimsnagpur.edu.in</td></tr> <tr> <td>Dr Adil Ahmad Khan</td><td>All India Institute of Medical Sciences, Patna</td><td>Department of Cardiology, Patna - Aurangabad Rd, Phulwari Sharif, Patna, Bari Khagaul, Bihar 801507 Patna BIHAR</td><td>9808688641 adil.amu@gmail.com</td></tr> <tr> <td>Dr Sarita agrawal</td><td>All India Institute of Medical Sciences,</td><td>Room no. 3117, Medical College</td><td>8518881744</td></tr> </tbody> </table>	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email	Dr Anish Keepanasseril	Jawaharlal Institute of Postgraduate Medical Education & Research	Department of Gynaecology, JIPMER Campus Rd, Gorimedu, Dhanvantari Nagar, Puducherry, 605006 PONDICHERRY	8903307141 keepan_r@yahoo.com	Dr Surender Deora	All India Institute of Medical Sciences , Jodhpur	Room no:45, OPD BLOCK, 4TH FLOOR, C-BLOCK, Marudhar Industrial Area, 2nd Phase, M.I.A. 1st Phase, Basni, Basni, Jodhpur, Rajasthan 342005 Jodhpur RAJASTHAN	8003996715 deoras@aiimsjodhpur.edu.in	Dr Vatsla Dadhwal	All India Institute of Medical Sciences, Delhi	Room 714, Mother and Child Block, Ansari Nagar, New Delhi 110608 South West DELHI	9811015979 vatslad@gmail.com	Dr Arijit Kumar Ghosh	All India Institute of Medical Sciences, Nagpur	Room No: 140, OPD Block, MIHAN, Nagpur, Sumthana, Dahegaon, Maharashtra 441108 Nagpur MAHARASHTRA	8007658278 akumarg@aiimsnagpur.edu.in	Dr Adil Ahmad Khan	All India Institute of Medical Sciences, Patna	Department of Cardiology, Patna - Aurangabad Rd, Phulwari Sharif, Patna, Bari Khagaul, Bihar 801507 Patna BIHAR	9808688641 adil.amu@gmail.com	Dr Sarita agrawal	All India Institute of Medical Sciences,	Room no. 3117, Medical College	8518881744
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**Details of Ethics Committee**

		110029 New Delhi DELHI	
Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
BIOMEDICAL RESEARCH ETHICS COMMITTEE, Pt.B.D.Sharma PGIMS/ UHS, Rohtak	Approved	23/01/2024	No
ETHICS AND SCIENTIFIC REVIEW COMMITTEE, M.G.M.MEDICAL COLLEGE	Approved	20/05/2024	No
Ethics Committee of Amrita School of medicine	Approved	30/01/2024	No
ETHICS COMMITTEE OF BANGALORE MEDICAL COLLEGE AND RESEARCH INSTITUTE	Approved	28/12/2023	No
ETHICS COMMITTEE, ARMED FORCES MEDICAL COLLEGE	Approved	06/05/2024	No
ETHICS COMMITTEE, GSVM, MEDICAL COLLEGE, KANPUR	Approved	19/12/2023	No
ETHICS COMMITTEE, GUNTUR MEDICAL COLLEGE & GOVT. GENERAL HOSPITAL	Approved	19/01/2024	No
ETHICS COMMITTEE, OSMANIA MEDICAL COLLEGE	Approved	01/03/2024	No
ETHICS COMMITTEE, PATNA MEDICAL COLLEGE	Submitted/Under Review	No Date Specified	No
ETHICS COMMITTEE, S.M.S MEDICAL COLLEGE	Approved	20/02/2024	No
ETHICS COMMITTEE, S.P.MEDICAL COLLEGE, BIKANER	Approved	01/02/2024	No
ETHICS COMMITTEE- AIMS, THRISSUR	Approved	27/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE, CHRISTIAN MEDICAL COLLEGE AND HOSPITAL	Approved	03/02/2024	No
INSTITUTIONAL ETHICS COMMITTEE, MEDICAL COLLEGE, KOLKATA	Approved	15/01/2024	No



INSTITUTIONAL ETHICS COMMITTEE, SHER-I-KASHMIR INSTITUTE OF MEDICAL SCIENCES	Approved	04/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE- CIHSR	Approved	17/01/2024	No
INSTITUTE ETHICS COMMITTEE, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, DELHI	Approved	05/02/2024	No
INSTITUTE ETHICS COMMITTEE,, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RAIPUR	Approved	22/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE, M/S. KING GEORGE HOSPITAL VISHAKAPATNAM	Approved	19/12/2023	No
Institutional Ethics Committee (Human Studies) for Observational Studies-JIPMER	Approved	20/03/2024	No
INSTITUTIONAL ETHICS COMMITTEE FOR CLINICAL TRIAL, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NAGPUR	Approved	30/03/2024	No
INSTITUTIONAL ETHICS COMMITTEE MAMC	Approved	25/04/2024	No
INSTITUTIONAL ETHICS COMMITTEE, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR	Approved	13/02/2024	No
INSTITUTIONAL ETHICS COMMITTEE, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, PATNA	Approved	08/04/2024	No
INSTITUTIONAL ETHICS COMMITTEE, BURDWAN MEDICAL COLLEGE	Approved	01/02/2024	No
INSTITUTIONAL ETHICS COMMITTEE, DATTA MEGHE INSTITUTE OF HIGHER EDUCATION AND RESEARCH	Approved	31/01/2024	No
INSTITUTIONAL	Approved	22/01/2024	No



ETHICS COMMITTEE, DAYANAND MEDICAL COLLEGE			
INSTITUTIONAL ETHICS COMMITTEE, GAJRA RAJA MEDICAL COLLEGE, GWALIOR	Approved	09/02/2024	No
INSTITUTIONAL ETHICS COMMITTEE, GAUHATI MEDICAL COLLEGE & HOSPITAL, GUWAHATI	Approved	19/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE, GOVERNMENT MEDICAL COLLEGE, KOZHIKODE	Approved	15/12/2023	No
INSTITUTIONAL ETHICS COMMITTEE, KING GEORGES MEDICAL UNIVERSITY	Approved	19/04/2024	No
INSTITUTIONAL ETHICS COMMITTEE, M.K.C.G. MEDICAL COLLEGE	Approved	27/12/2023	No
INSTITUTIONAL ETHICS COMMITTEE, MADRAS MEDICAL COLLEGE, CHENNAI	Approved	25/11/2023	No
INSTITUTIONAL ETHICS COMMITTEE, MADURAI MEDICAL COLLEGE & GOVT. RAJAJI HOSPITAL, MADURAI	Approved	12/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE, NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCES	Approved	19/02/2024	No
INSTITUTIONAL ETHICS COMMITTEE, Pt JNM MC, Raipur	Approved	11/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE, R.N.T.MEDICAL COLLEGE	Approved	06/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE, S.C.B.MEDICAL COLLEGE & HOSPITAL	Approved	10/04/2024	No
INSTITUTIONAL	Approved	29/12/2023	No



ETHICS COMMITTEE, SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES			
INSTITUTIONAL ETHICS COMMITTEE, SETH GS MEDICAL COLLEGE AND KEM HOSPITAL	Approved	20/03/2024	No
INSTITUTIONAL ETHICS COMMITTEE, Smt.NHL Municipal Medical College	Approved	12/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE, THANJAVUR MEDICAL COLLEGE	Approved	13/02/2024	No
INSTITUTIONAL ETHICS COMMITTEE, VARDHMAN MAHAVIR MEDICAL COLLEGE	Approved	19/10/2024	No
INSTITUTIONAL ETHICS COMMITTEE,, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RISHIKESH	Approved	19/01/2024	No
INSTITUTIONAL ETHICS COMMITTEE-HIMS, HASSAN	Approved	04/12/2023	No
Institutional Human Ethics Committee, Coimbatore Medical College	Approved	18/01/2024	No
Institutional Research Advisory Committee, Goa Medical College	Approved	29/02/2024	No
INSTITUTIONAL REVIEW BOARD, CHRISTIAN MEDICAL COLLEGE	Approved	09/08/2024	No
Sir Ganga Ram Hospital Ethics Committee	Approved	27/07/2024	No
SMIMS Ethics Committee	Approved	05/02/2024	No

**Regulatory Clearance  
Status from DCGI**

Status	Date
Not Applicable	No Date Specified

**Health Condition /  
Problems Studied**

Health Type	Condition
Patients	Diseases of the circulatory system complicating pregnancy, childbirth and the puerperium

**Intervention /  
Comparator Agent**

Type	Name	Details
Intervention	Protocolised Cardio Obstetric Care	A protocol for managing heart disease in pregnant women will



		be developed in the first observational phase. The sites randomized to Protocolised Cardio Obstetric Care group, will follow the management pattern as suggested by the newly developed protocol. This phase will last for about twenty four months (till all the patients enrolled during the phase, complete their pregnancy and the mandatory follow up)
	Comparator Agent	Enhanced usual Care Group
		Comparator group will include the sites randomized to the enhanced usual care. These sites will follow the usual care followed as before for managing pregnant women. This phase will last for about twenty four months (till all the patients enrolled during the phase, complete their pregnancy and the mandatory follow up)
Inclusion Criteria	<b>Inclusion Criteria</b>	
	Age From	18.00 Year(s)
	Age To	60.00 Year(s)
	Gender	Female
	Details	All consecutive pregnant women with   known or newly detected heart diseases mentioned below, seeking antenatal care in the participating sites will be eligible for inclusion.   Structural Heart disease- congenital or acquired  Arrhythmic heart disease   Ischemic heart disease  Aortic diseases   Pulmonary vascular disease   
Exclusion Criteria	<b>Exclusion Criteria</b>	
	Details	Patients with hypertensive disorders of pregnancy or gestational diabetes mellitus without any of the above inclusion criteria Patients below the age of 18 Patients who are not able to or not willing to give informed consent. Patients who are part of another trial
Method of Generating Random Sequence	Other	
Method of Concealment	Not Applicable	
Blinding/Masking	Not Applicable	
Primary Outcome	<b>Outcome</b>	<b>Timepoints</b>
	Composite Maternal adverse events as mentioned below Maternal death Resuscitated cardiac arrest	42 days after delivery
	New or worsening maternal heart failure requiring treatment escalation or hospitalization (Left-sided heart failure (HF) or pulmonary edema; right-sided HF)  New onset or recurrent sustained cardiac	



arrhythmia requiring treatment	
Systemic thrombo-embolism	
Hemorrhagic complications (Major bleed or minor bleed as per ISTH Criteria)	
Venous thrombo-embolism (DVT / PE / Invictus trial)	
Cerebrovascular accident / Stroke	
Infective endocarditis	
Prosthetic valve thrombosis	
Aortic dissection developing during pregnancy	
Acute coronary syndrome / SCAD	
Performance of urgent cardiac intervention up to 6th postpartum week ( like PTMC, Pericardiocentesis, RF ablation)	

**Secondary Outcome**

Outcome	Timepoints
Maternal Death	6 months
Decline in NYHA functional class ? 2 during pregnancy	42 days after delivery
Cardiac hospitalization	Antenatal period and upto 6 weeks in the post natal period
PPH	Peripartum Period
Gestational diabetes	Antenatal Period
Mode of delivery (If LSCS – emergency LSCS / elective LSCS, Cardiac indication / obstetric indication)	Peripartum Period
Hypertensive disorders of pregnancy	Antenatal Period
PROM- Premature rupture of membranes	During delivery
Urgent unplanned cardiac hospitalization	Antenatal period and upto 6 weeks in the post natal period
Miscarriage (fetal loss up to 20 weeks)	First 20 weeks in the antenatal period
Fetal loss after 20th week.	First 20 weeks in the antenatal period
Small for gestational age	During Delivery
Low birth weight (less than 2.5 kg irrespective of gestational age)	During delivery
Preterm birth	During Delivery
Admission to neonatal intensive care unit	6 weeks in the post natal period



	Neonatal death	6 weeks in the post natal period
	Congenital anomalies (including CHD) in the new born	6 weeks in the post natal period
	Elective cardiac interventions done (Lysis, ablation, Balloon, surgery)	Antenatal period and upto 6 weeks in the post natal period
	Duration of stay in ICU	Antenatal period and upto 6 weeks in the post natal period
Target Sample Size	<b>Total Sample Size=3300</b> <b>Sample Size from India=3300</b> <b>Final Enrollment numbers achieved (Total)=</b> Applicable only for Completed/Terminated trials <b>Final Enrollment numbers achieved (India)=</b> Applicable only for Completed/Terminated trials	
Phase of Trial	N/A	
Date of First Enrollment (India)	01/04/2024	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	<b>Years=4</b> <b>Months=0</b> <b>Days=0</b>	
Recruitment Status of Trial (Global)	Not Yet Recruiting	
Recruitment Status of Trial (India)	Open to Recruitment	
Publication Details	N/A	
Brief Summary	<p><b>Background:</b> Heart disease complicates 1- 4% of pregnancies. The number of women presenting with heart disease during pregnancy is increasing. Despite the reduction in maternal mortality in India over the past two decades, cardiac contribution to maternal mortality is increasing. Data on pregnant women with heart disease (PWWHD) representative of our nation, local risk scores and guidelines /protocols are lacking.</p> <p><b>Novelty:</b> A pragmatic protocol for managing PWWHD will be developed and tested. Data representative of India will be collected. Findings may influence care and pregnancy outcomes in other low and middle-income countries.</p> <p><b>Aims and Objectives:</b> To study profile and fetomaternal outcomes of PWWHD in India, to understand the existing practice patterns in care offered to PWWHD in India, develop a customized protocol for managing PWWHD appropriate for India, and assess its impact on outcomes compared to usual care</p> <p>To develop a regional score for risk stratifying PWWHD in India to enable</p>	





targeted management.

**Methods:** We propose a multicentric study covering 24 states in India. During Phase 1 of the study, the practice patterns in managing PWWHD will be assessed across 50 centres in India and a step-wise protocol to improve outcome will be developed. During phase 2, a cluster randomized study will be conducted among 40 average-large centres across India to assess the effectiveness of the protocolized cardio-obstetric care in improving outcomes compared to usual care.

**Expected outcome:** A protocol for managing PWWHD in India will be developed. A regional score for risk-stratifying PWWHD in India will be developed and validated. The contribution of heart disease to maternal mortality in India will be reduced in the years that follow.