

Protocol

A study protocol for assessing the efficacy of Nagabala-Arjunadi Yoga and Arogyavardhini Rasa in the management of post-myocardial infarction as an add-on to the standard care: a standard controlled clinical trial

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ABSTRACT

Background: Myocardial infarction (MI) is a major cause of cardiovascular morbidity and mortality. Despite advances in reperfusion and standard pharmacological management, patients may develop left ventricular dysfunction, adverse cardiac remodelling, recurrent ischemic symptoms, reduced functional capacity, and impaired quality of life. Nagabala-Arjunadi Yoga has shown beneficial effects on cardiac symptoms, left ventricular ejection fraction (LVEF), and quality of life in previous study. Arogyavardhini Rasa, with its Hridya (Cardioprotective), Lekhana (Scraping action), and Medohara (Hypolipidemic) properties, may provide additional cardiovascular benefits. However, evidence regarding their combined efficacy in post-MI management remains limited. Objectives were to evaluate the efficacy of Nagabala-Arjunadi Yoga and Arogyavardhini Rasa as add-on to standard care in post-MI patients.

Methods: This prospective, open-label, randomized, standard-controlled clinical trial will enrol 106 post-MI patients. Participants will be allocated to receive either Nagabala-Arjunadi Yoga and Arogyavardhini Rasa alongside standard care or standard care alone for 12 weeks. Primary outcomes will include changes in LVEF, left ventricular end-diastolic volume (LVEDV), left ventricular end-systolic volume (LVESV), N-terminal pro-B-type natriuretic peptide (NT-proBNP), angina severity, fatigue, dyspnoea, and functional capacity. Health-related quality of life (HRQoL) will be assessed using the MacNew questionnaire as a secondary outcome. Assessments will be performed at baseline and post-treatment. Appropriate parametric and non-parametric statistical tests will be applied, with $p < 0.05$ considered statistically significant.

Conclusions: The study will evaluate whether these Ayurvedic formulations, as add-on to standard care, improve cardiac function, remodelling parameters, NT-proBNP levels, ischemic symptoms, functional capacity, and quality of life in post-MI patients.

Trial Registration: The trial is registered with Clinical Trial Registry of India (CTRI). CTRI/2026/07/114947.

Keywords: Arogyavardhini rasa, Hridroga, Left ventricular ejection fraction, Left ventricular remodeling, Nagabala-Arjunadi Yoga, N-terminal pro-B-type natriuretic peptide, Post-myocardial infarction

INTRODUCTION

Myocardial infarction (MI) is the most common form of coronary heart disease.¹ From a modern biomedical perspective, MI results from acute ischemia due to

coronary artery occlusion, leading to ischemic necrosis of myocardial tissue. Although advances in reperfusion therapy and pharmacological management have reduced acute mortality, post-MI patients continue to experience residual myocardial dysfunction, including: left

ventricular systolic and diastolic dysfunction, adverse ventricular remodelling, persistent inflammation and oxidative stress, neurohormonal activation (RAAS, sympathetic overactivity), reduced functional capacity and quality of life. Thus, post-MI management focuses not only on secondary prevention (antiplatelets, statins, ACE inhibitors, β -blockers) but also on myocardial recovery, prevention of remodelling, and functional rehabilitation. However, current conventional therapies primarily target risk reduction and survival, with limited emphasis on tissue rejuvenation and holistic functional restoration, creating a scope for integrative add-on therapies.² Coronary artery disease (CAD) is the major pathophysiological driver of MI and number one cause of HF.

Nagabala-Arjunadi Yoga contains ingredients that have proven Hridya (Cardioprotective), Rasayana (Rejuvenative), Balya (Strength-promoting), Lekhana (Scraping action), and Vatanulomana properties (Normalization of Vata functions).^{3,4} Since MI predominantly occurs due to atherosclerotic obstruction of the epicardial coronary arteries, therapeutic strategies addressing both myocardial recovery and underlying metabolic disturbances are essential. Arogyavardhini Rasa, possessing Hridya (Cardioprotective) and Medohara (Hypolipidemic) properties, was therefore selected along with Nagabala-Arjunadi Yoga for the present study.

Previous clinical research on Nagabala-Arjunadi Yoga as an add-on to conventional therapy in post-MI patients demonstrated significant improvements in fatigue, dyspnoea, angina severity, LVEF, and HRQoL. However, the previous study primarily focused on symptomatic improvement and overall cardiac function, without evaluating objective indicators of cardiac remodelling and heart failure progression.

Following MI, adverse left ventricular remodelling is a major determinant of long-term morbidity, development of heart failure, and cardiovascular mortality.⁵ Parameters such as LVEDV, LVESV, and NT-pro BNP are recognized markers of ventricular remodelling and cardiac dysfunction. Till date, no clinical study has evaluated the combined effect of Nagabala-Arjunadi Yoga and Arogyavardhini Rasa on these parameters in post-MI patients.

The present study has therefore been designed to assess whether the addition of Nagabala-Arjunadi Yoga and Arogyavardhini Rasa to standard care can improve left ventricular function, attenuate adverse cardiac remodelling, reduce NT-pro BNP levels, enhance functional capacity, alleviate post-MI symptoms, and improve HRQoL. The findings are expected to provide objective clinical evidence regarding the role of these Ayurvedic interventions as adjunctive therapy in post-MI rehabilitation and may contribute to the development of integrative strategies for long-term cardiovascular care.

Aim and objectives

Aim of the study is to assess the add on efficacy of Nagabala-Arjunadi Yoga along with Arogyavardhini Rasa to the standard conventional treatment in the management of post-MI.

Primary objectives

Primary objectives were to assess the efficacy of add on oral administration of Nagabala-Arjunadi Yoga along with Arogyavardhini Rasa in LV function LVEF, cardiac remodelling changes in LVEF, LVEDV and LVESV by Echocardiography and NT-pro BNP biomarker and to assess the efficacy of trial drugs in angina severity by Canadian cardiovascular society angina scale and functional capacity assessed by NYHA classification.⁶⁻⁸

Secondary objective

Secondary objectives were to evaluate role of trial drugs the improvement in the HRQoL by MAC NEW assessment criteria in the patients of post-MI.⁹

Outcome

Primary outcomes include improvement in LV function in terms of LVEF, LVEDV and LVESV, NT pro-BNP biomarker and improvement in post-MI ischemic outcome of the patient in terms of fatigue, angina severity and frequency, dyspnoea and functional capacity. Secondary outcome include improvement in MAC NEW HRQoL in the post-MI patients

METHODS

Patients and public involvement

Trial design

This study is prospective, open-labelled, randomized standard controlled parallel group clinical trial with an allocation ratio of 1:1. It is superiority trial designed to compare efficacy of add-on oral administration of Nagabala-Arjunadi Yoga along with Arogyavardhini Rasa to standard care and standard care alone in the management of post-MI. Randomization will be done by computer generated randomisation method to ensure unbiased allocation (<https://www.randomizer.org>).

Study setting

The study will be conducted in the department of Kayachikitsa, Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar. Pre-diagnosed cases of MI visiting OPD/IPD of Kayachikitsa and chest-TB OPD of Kayachikitsa will be screened on the basis of diagnostic and inclusion criteria such as history of MI with its chronicity, history of thrombolysis and surgery related to CVD, investigations including CBC, FBS, lipid profile,

LFT (SGPT and SGOT), RFT (Blood urea and S. Creatinine), ECG and 2D echocardiography. Only those fulfilling all the criteria will be enrolled in the study.

Sample size calculation

sample size was calculated on the basis of previous research work done on post-MI based on change in LVEF taken as the primary outcome variable. Observing a mean difference of 6.07% in EF between the trial and control group with standard deviation of 10% at a 95% of confidence level and 80% of power, sample size was calculated using formula

$$n=2(Z_{\alpha/2}+Z_{\beta/2})^2\sigma^2/\Delta^2$$

The required sample size is 44 subjects per group. Considering a dropout rate of 20%, 53 patients will be enrolled in each group, making total sample size of 106 patients.

Diagnostic criteria

Post-MI refers to period after the acute phase of MI, during which patient survives but has structural, functional and metabolic changes in the heart due to damaged myocardium.

The pre-diagnosed cases of MI as per the WHO European MI registry criteria having history of occurrence of event of MI before 2 weeks and chronicity of 5 years of MI under the conventional treatment will be recruited into the present clinical trial fulfilling inclusion and exclusion criteria.¹⁰

Inclusion criteria

Patients of either gender, religion and caste fulfilling the diagnostic criteria of post MI between age group 30-70 years will be included in this clinical trial. Only those willing to give written informed consent, comply with the study protocol including follow-up visits and outcome assessment will be enrolled.

Exclusion criteria

Participants diagnosed with acute MI due to non-atheromatous causes or acute MI associated with any other heart disease like valvular heart disease or congestive heart failure will be excluded from the study. Patients with ejection fraction less than 35%, patients with recurrent MI or those who had undergone coronary artery bypass grafting or history of MI within 2 weeks or unstable angina or chronicity more than 5 years will also not be considered for inclusion. Patients with liver or kidney disorders or severe or uncontrolled malignant hypertension or patients with uncontrolled type 2 diabetes and patients of type 1 diabetes or insulin dependent type 2 diabetes or COPD patients or patients with severe/serious arrhythmias or presenting with congestive

cardiac failure or ascites will also be excluded from the study.

Intervention and control details

Intervention group (Group A-Trial drugs along with standard care)

Participants in group A will receive Nagabala-Arjunadi Yoga orally in dose of 3 tablets (500 mg each) three times a day Apana Kale (half an hour before breakfast, lunch and dinner) with Luke-warm cow milk as Anupana and Arogyavardhini Rasa orally in dose of 1 capsule (250 mg) twice a day after breakfast and dinner with warm water as add-on to standard care as treatment. The duration of intervention will be 12 weeks.

To minimize potential pharmacokinetic and pharmacodynamic interactions between Ayurvedic and standard care medications, a minimum interval of 1 hour will be maintained between the administration of trial drugs and standard care medications.

Control group (Group B-standard care alone)

Participants in group B will receive standard care treatment alone (Angiotensin converting enzyme inhibitors, Dual antiplatelet therapy, Beta blockers, Statins-as per advice) for duration of 12 weeks.

Participant timeline

Table 1 presents the schedule of enrolment, interventions, assessments, and follow-up throughout the study period. Eligible participants will undergo screening, informed consent, demographic data collection, medical history recording, physical examination, baseline laboratory investigations, electrocardiography, echocardiography, NT-pro BNP estimation, and health-related quality of life assessment prior to randomization. Following allocation, participants will receive the assigned intervention for 12 weeks and will be monitored through weekly follow-up visits (± 3 days).

During each visit, physical examination, vital signs, assessment of clinical symptoms, treatment compliance, and monitoring of adverse events will be carried out. Echocardiographic parameters (LVEF, LVEDV, and LVESV), laboratory investigations, NT-pro BNP levels, and quality-of-life assessments will be repeated at the end of the treatment period to evaluate therapeutic outcomes.

An additional follow-up assessment will be conducted 8 weeks after completion of treatment, which may be performed telephonically, to assess the sustainability of treatment effects and identify any delayed adverse events. The detailed participant timeline is presented in Table 1.

Table 1: Participant timeline.

Periods	Screening	Intervention phase												Follow-up
Visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	
Visit name	Screening period	Randomization	-	-	-	-	-	-	-	-	-	-	End of the treatment period	Can be telephonically
Visit window (in days)	1-7	After screening	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	After 8 weeks
Informed consent	-	√	-	-	-	-	-	-	-	-	-	-	-	-
Demographics	-	√	-	-	-	-	-	-	-	-	-	-	-	-
Medical history	√	-	-	-	-	-	-	-	-	-	-	-	-	-
Physical examination	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Vital signs	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Assessment of signs and symptoms	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Investigations BT (Urine routine and microscopic)	-	√	-	-	-	-	-	-	-	-	-	-	-	-
Investigations BT and AT (CBC, FBS, lipid profile, SGPT, SGOT, Blood urea, S. creatinine, ECG, 2D ECHO-LVEF, LVEDV, LVESV)	-	√	-	-	-	-	-	-	-	-	-	-	√	-
NT pro-BNP	-	√	-	-	-	-	-	-	-	-	-	-	√	-
HRQoL scale	-	√	-	-	-	-	-	-	-	-	-	-	√	√
Dispense study drugs	-	√	√	√	√	√	√	√	√	√	√	√	√	-
Adverse events	-	-	√	√	√	√	√	√	√	√	√	√	√	-

*CBC: Complete blood count, FBS: Fasting blood sugar, SGPT: Serum glutamic pyruvate transaminase, SGOT: Serum glutamic oxaloacetic transaminase, ECG: Electrocardiography, ECHO: Echocardiography, LVEF: Left ventricular ejection fraction, LVEDV: Left ventricular end diastolic volume, LVESV: Left Ventricular end systolic volume, NT-pro BNP: N-terminal pro-B-type natriuretic peptide, HRQoL: Heart specific health related quality of life.

Pathya-Apathya (Diet and lifestyle regimen)

All participants will be advised to follow diet and lifestyle regimen specific to cardiovascular disease throughout the study period. They will be encouraged to consume freshly prepared, light, easily digestible, and balanced meals including whole grains, green leafy vegetables, seasonal fruits, pulses, low-fat dairy products, and foods rich in dietary fibre, while restricting excessive salt, saturated fats, trans fats, refined sugars, and processed foods.

Participants will be advised to avoid deep-fried foods, bakery products, fast foods, tobacco in any form, alcohol, and sugar-sweetened beverages. They will also be instructed to maintain adequate hydration, consume meals at regular intervals, avoid overeating, and ensure adequate sleep. Moderate physical activity, such as regular walking as tolerated along with stress-reducing practices, will be encouraged.¹¹

Drug compliance and treatment adherence

Drug compliance will be ensured throughout the study by providing participants with clear verbal instructions regarding the dosage, frequency, timing, and method of administration of the study medications. The trial drugs will be dispensed at each scheduled follow-up visit, and participants will be advised to adhere to the prescribed treatment regimen and continue their standard conventional therapy as recommended by the treating physician.

Treatment adherence will be assessed through participant interviews, review of medication intake records, and pill counts by counting the unused tablets and capsules returned by the participants.

Participants demonstrating poor adherence will receive appropriate counselling and reinforcement regarding the importance of treatment compliance. Reasons for missed doses or discontinuation of medication will be documented in the Case record form (CRF).

Withdrawal criteria

The participant will be withdrawn from the study if any of the following criteria are met: Voluntary withdrawal- Withdrawal of informed consent or the participant's decision to discontinue participation at any time, without providing a reason. Non-compliance with protocol- Unwillingness or inability to comply with the study protocol requirements despite counselling and reminders. Adverse events- Occurrence of serious adverse events or other adverse reactions that, in the judgment of the investigator, are related to the study drug and pose a risk to the participant's health or safety. Lost to follow-up- failure to attend scheduled visits or respond to communication attempts for a specified duration.

Data collection, management and analysis***Data collection methods***

Data will be collected using a predesigned CRF developed specifically for this study. Baseline data will include demographic details, medical history, duration since MI, cardiovascular risk factors, current medications history, physical examination findings, and vital parameters. Clinical assessments will be performed at baseline and at each scheduled follow-up visit. These will include a detailed physical examination, systemic examination, vital signs and assessment of clinical symptoms.

Subjective parameters will be assessed using standardized assessment tools, including the Canadian Cardiovascular Society (CCS) angina grading scale, New York Heart Association (NYHA) functional classification, fatigue and dyspnoea assessment, and the Mac New health-related quality of life questionnaire.

Objective assessment will include echocardiographic parameters (LVEF, LVEDV), and LVESV, and NT-pro BNP levels. Echocardiographic assessments will be performed by qualified personnel using standardized procedures to minimize inter-observer variability.

Data will be collected at baseline, throughout the 12-week intervention period, and during the post-treatment follow-up visit. Treatment compliance will be assessed through participant interviews and drug accountability records.

Data management

All study-related data will be recorded in a predesigned CRF and subsequently entered into a password-protected electronic database. All study records, including consent forms, CRFs, laboratory reports, and electronic datasets, will be securely stored throughout the study period and retained as per institutional and regulatory requirements. Access to study data will be restricted to authorized personnel involved in the conduct, monitoring, and analysis of the trial.

Data confidentiality

Confidentiality of the study participants will be strictly maintained throughout the study period. All clinical data, investigation reports, and case record forms will be used only for research purposes and assessable only to the investigators and research supervisors.

Data safety and monitoring

The study will be conducted under the oversight of the institutional ethics committee (IEC), Institutional review committee (IRC), and departmental review committee (DRC) of the ITRA, Jamnagar. Regular monitoring will

be carried out to ensure compliance with the approved study protocol, Good Clinical Practice (GCP) guidelines and applicable institutional regulations.

All study-related data will be reviewed periodically for accuracy, completeness, consistency and protocol adherence. Source documents, CRFs, and electronic data records will be verified at regular intervals to identify and resolve any discrepancies. The study records will be maintained securely and made available for audit or inspection by the relevant institutional and regulatory authorities, whenever required.

Data analysis

The information gathered based on the observation made about various parameters will be subjected to statistical analysis in terms of mean, standard deviation (SD) and standard error (SE). General data will be subjected to suitable statistical analysis such as: Descriptive statistics for demographic data, Paired t-test for paired continuous data i.e., within the groups, and unpaired t test will be applied for between groups continuous data. Wilcoxon Signed-Rank Test will be used for non-parametric data within the groups and Mann-Whitney U Test for comparing between groups with non-parametric data. The data generated in the clinical study will be analyzed by applying appropriate statistical method also. After preparing the master chart of all the required data in a Microsoft Excel worksheet, statistical calculations will have made with the help of SPSS software. The results will have interpreted as: Significant $p < 0.05$, Highly significant $p < 0.01$, very highly significant $p < 0.001$, Insignificant $p > 0.05$.

Ethics and dissemination

Ethical approval will be obtained from the institutional ethics committee before commencement of participant recruitment, and the trial will be prospectively registered with the Clinical Trials Registry-India (CTRI). Patient safety will be monitored throughout the study by regular clinical assessments, physical examinations, vital sign monitoring, and laboratory investigations. Any adverse events (AEs) or serious adverse events (SAEs) occurring during the study period will be documented, evaluated for severity and reported to the IEC and the pharmacovigilance cell of the ITRA in accordance with institutional guidelines.

Any protocol amendments will be communicated to the relevant regulatory and ethical authorities for approval before implementation.

The findings of this study will be disseminated through publication in peer-reviewed journals, presentation at national and international scientific conferences, and academic forums. Study results will be reported transparently irrespective of the nature or direction of the findings. Dissemination of the outcomes is expected to

contribute to the evidence base regarding the role of Ayurvedic interventions as adjunctive in the management of post-MI patients.

DISCUSSION

The present study has been designed to generate high-quality clinical evidence regarding the role of Ayurvedic interventions as adjuncts to standard care in the management of post-MI patients. Unlike previous studies that predominantly focused on symptomatic improvement and LVEF, the present protocol incorporates comprehensive evaluation of ventricular remodelling through echocardiographic parameters (LVEF, LVEDV, and LVESV) and the cardiac biomarker NT-pro BNP. Assessment of these objective outcome measures, together with validated clinical scales and health-related quality-of-life assessment, is expected to provide a multidimensional evaluation of therapeutic response.

The study employs a randomized standard-controlled design with predefined outcome measures, systematic follow-up, and structured safety monitoring to ensure methodological rigor and reproducibility. Simultaneous evaluation of objective cardiac parameters and patient-reported outcomes will facilitate a comprehensive assessment of both physiological recovery and functional improvement following MI.

An important feature of this protocol is the evaluation of Ayurvedic formulations as add-on therapy rather than as an alternative to evidence-based conventional treatment. This integrative approach reflects contemporary clinical practice and may provide clinically relevant evidence regarding the complementary role of Ayurvedic interventions in cardiac rehabilitation. Furthermore, the inclusion of echocardiographic indices of ventricular remodelling and NT-pro BNP, which have not been routinely evaluated in previous Ayurvedic clinical studies on post-MI patients, enhances the scientific value and novelty of the trial.

The findings of this study are expected to strengthen the evidence base for integrative management of post-MI patients and may serve as a basis for future multicentric clinical trials investigating long-term cardiovascular outcomes and rehabilitation strategies.

CONCLUSION

The results of this study are expected to provide scientific evidence regarding the potential role of these Ayurvedic formulations in promoting myocardial recovery and preventing adverse cardiac remodelling following MI. If successful, the study may support the integration of evidence-based Ayurvedic interventions into comprehensive post-MI management strategies and contribute to improving long-term cardiovascular outcomes and patient well-being.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee of Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat, India.

Approval no.: PGT/7/-A/Ethics/2026-27/708

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