

Protocol

Efficacy of add-on Dusparshadi Kashaya and Chandraprabha Vati in the management of grade 2 to 3b chronic kidney disease: a structured study protocol of open labelled randomized standard controlled clinical trial

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Received: 07 July 2026

Revised: 09 September 2026

Accepted: 07 October 2026

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ABSTRACT

Background: Chronic kidney disease (CKD) is a progressive disorder characterized by persistent renal dysfunction, commonly associated with diabetes mellitus and hypertension. Despite advances in conventional management, CKD remains a major global health burden due to its progressive course and complications. In Ayurveda, its clinical manifestations may be correlated with Vrikkaroga described in Bhaishajyaratnavali.

Methods: This single-center, open-label, randomized, standard-controlled clinical trial will enroll participants with grade 2-3 B CKD diagnosed according to kidney disease quality of life (KDIGO) 2024 guidelines. Eligible participants will be randomly allocated to an intervention or control group. The intervention group will receive standard medical treatment plus Dusparshadi Kashaya (120 mL twice daily before meals) and Chandraprabha Vati (500 mg, two tablets twice daily after meals) for 60 days, while the control group will receive standard medical treatment. The primary outcome will be the change in estimated glomerular filtration rate (eGFR) from baseline to day 60. Secondary outcomes will include changes in serum creatinine, serum urea, hemoglobin, and quality of life assessed using the KDQOL™-36 questionnaire. Additional outcomes will include dialysis requirement and mortality. Data will be analyzed using statistical tests, with $p < 0.05$ considered statistically significant.

Conclusions: This study will assess the efficacy and safety of Dusparshadi Kashaya and Chandraprabha Vati as adjuncts to standard care in grade 2-3b CKD and may provide evidence for their potential to improve renal function, quality of life, and clinical outcomes.

Trial Registration: The trial is registered with the Clinical Trials Registry of India (CTRI) (CTRI/2026/05/110662).

Keywords: Ayurveda, Chandraprabha Vati, Chronic kidney disease, Dusparshadi Kashaya

INTRODUCTION

Chronic kidney disease (CKD) is a progressive, multifactorial condition influenced by both non-modifiable factors (age, genetics, ethnicity) and modifiable ones (type 2 diabetes, hypertension, dyslipidemia). Early stages (1-2) are marked by kidney damage due to conditions like diabetes and obesity, while later stages (3-5) involve complications such as anemia,

mineral bone disorders, and hyperkalemia. The KDIGO 2024 classification uses the CGA system: Cause, GFR category (G1-G5), and Albuminuria category (A1-A3). In stage G1, the GFR is greater than 90 mL/min/1.73 m², indicating normal or high kidney function. Stage G2 represents a mildly decreased GFR, ranging from 60 to 89 mL/min/1.73 m². In stage G3a, the GFR is mildly to moderately decreased at 45 to 59 mL/min/1.73 m², while stage G3b indicates a moderately to severely decreased

GFR of 30 to 44 ml/min/1.73 m². Stage G4 is characterized by a severely decreased GFR of 15 to 29 ml/min/1.73 m². Finally, stage G5, with a GFR less than 15 ml/min/1.73 m², reflects kidney failure. Albuminuria, another important marker for kidney damage, is classified into three categories based on the albumin-to-creatinine ratio (ACR). A1 indicates normal to mildly increased albuminuria with an ACR of less than 30 mg/g (<3 mg/mmol). A2 represents moderately increased albuminuria with an ACR between 30 to 299 mg/g (3-30 mg/mmol), while A3 signifies severely increased albuminuria with an ACR greater than 300 mg/g (>30 mg/mmol).¹

The clinical features of Vrikkaroga described in Bhaishajyaratnavali exhibit notable similarities to the manifestations of CKD, particularly in the advanced stages. Symptoms such as Agnimandya (loss of appetite stage 4 CKD), Chardi (vomiting: stage 4 CKD), Sarvanga Vedana (skeletal abnormality due to hypocalcemia and secondary hyperparathyroidism), Shopha (generalized edema), Twakrukshata (dry scaly skin), Pandu (anemia due to erythropoietin deficiency), Nadeenoonamvegayuktam (hypertension), Mootrambinduroopena (oliguria/bladder dysfunction), Mootra with Rakta (hematuria), Hridroga (cardiovascular manifestations), Netraroga (ocular manifestations in CKD) and Dwajothabhangha (sexual dysfunction) reflect the systemic nature of renal impairment.² These correlations support the applicability of the Ayurvedic concept of Vrikkaroga in understanding and managing CKD.

In this study, two Ayurvedic medicines Dusparshadi Kashaya and Chandraprabha Vati will be evaluated as add-on therapy along with standard medical treatment.³⁻⁴ The ingredients of Dusparshadi Kashaya, such as Dusparsha (*Tragia involucrata* Linn), Punarnava (*Boerhaavia diffusa* Linn), Shalparni (*Desmodium gangeticum* DC), Prishniparni (*Ureria Picta* Desv), Brihati (*Solanum indicum* Linn.), Kantakari (*Solanum xanthocarpum* Schrad) and Gokshura (*Tribulus terrestris* Linn) are traditionally known for their Mutrala (diuretic) and Shothahara (anti-inflammatory) properties. Modern research suggests that these herbs may also have antioxidant, anti-inflammatory, and nephroprotective effects that may help protect kidney tissues and slow disease progression. Chandraprabha Vati is a classical Ayurvedic formulation widely used in urinary disorders. It may improve renal blood circulation, reduce inflammation, and exert antioxidant effects that protect epithelial and endothelial cells from oxidative damage, thereby helping preserve renal tissue integrity and prevent further deterioration.^{5,6}

CKD is often detected only after significant renal impairment has occurred due to its asymptomatic nature in the early stages. Early-stage CKD (Grade 2 3 B) offers a valuable therapeutic window where disease progression may be slowed and treatment outcomes are more favourable

compared to advanced stages requiring dialysis or renal replacement therapy. However, current management mainly focuses on symptom control and cardiovascular risk reduction, leaving a substantial residual risk of progression to end-stage kidney disease. Although several Ayurvedic studies have explored the management of CKD, most are limited to case reports and observational studies, with few randomized controlled trials evaluating Ayurvedic add-on therapies in early-stage CKD. Furthermore, the administration of Kashaya in high doses (120 mL), a practice commonly followed in Sri Lanka, has not been systematically evaluated for safety and tolerability in CKD patients. Therefore, the identification of safe and effective interventions for early-stage CKD is of considerable clinical importance and represents a significant unmet healthcare need.

Aim

Aim of the study is to evaluate the efficacy of oral administration of add-on Dusparshadi Kashaya and Chandraprabha Vati with the standard of care in the management of G2-G3b CKD.

Objectives

The primary objective of the study is to evaluate the effect of the trial drugs on improving the eGFR in participants with G2-G3b CKD. The secondary objectives are to assess their effects on reducing serum creatinine and serum urea levels, increasing hemoglobin levels, improving the quality of life as measured by the KDQOL™-36, and evaluating the safety of the trial drugs in participants with G2-G3b CKD.

METHODS

Trial design

This study is designed as a single-center, parallel-group, open-label, randomized, standard controlled clinical trial with a superiority framework. The trial aims to evaluate whether the trial intervention is more effective than standard treatment alone in participants with G2–G3b CKD. Eligible participants will be randomized in a 1:1 allocation ratio to either the intervention group or the control group using a computer-generated randomization sequence. (<https://www.randomizer.org>)

Study setting

The study will be conducted at the Department of Kayachikitsa, Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar, India. Participants with G2-G3b CKD attending the OPD and IPD of the Department of Kayachikitsa, or those referred from other departments of ITRA, GG Hospital, Jamnagar, and other nephrology hospitals, will be screened and on the basis of diagnostic and inclusion criteria. Baseline and post-intervention assessments will include renal function tests (blood urea,

serum creatinine, and eGFR, complete blood count (CBC), routine urine examination, fasting blood sugar (FBS), postprandial blood sugar (PPBS), ultrasonography of the kidneys, ureters, and bladder (USG KUB), serum ferritin, serum iron, total iron-binding capacity (TIBC), and parathyroid hormone (PTH) levels to evaluate treatment outcomes. Safety will be monitored through liver function tests, including SGPT, SGOT and serum bilirubin levels.

Diagnostic criteria

The diagnosis of CKD will be established in accordance with the KDIGO 2024 Clinical Practice Guideline. Participants with an eGFR of 30-89 ml/min/1.73 m², corresponding to GFR categories G2–G3b, will be screened for eligibility.

Elevated serum creatinine (>1.4 mg/dl) and serum urea (>43 mg/dl) will be considered supportive biochemical findings. Participants fulfilling the diagnostic criteria and meeting all the inclusion and exclusion criteria will be recruited into the present clinical trial.

Inclusion criteria

Patients of either gender, religion, or caste, aged 18-70 years, fulfilling the diagnostic criteria for CKD stages G2-G3b will be included in this clinical trial. Only those who are willing to provide written informed consent and comply with the study protocol, including scheduled follow-up visits and outcome assessments, will be enrolled.

Exclusion criteria

Participants will be excluded if they have renal artery stenosis, renal neoplasms, or congenital renal disorders such as autosomal dominant or autosomal recessive polycystic kidney disease, congenital nephrotic syndrome, Alport syndrome, Fabry disease, or juvenile nephronophthisis. Patients currently undergoing dialysis therapy or scheduled for renal transplantation will also be excluded.

Additional exclusion criteria include uncontrolled hypertension (systolic blood pressure ≥ 160 mmHg or diastolic blood pressure ≥ 100 mmHg confirmed by repeated measurements within 2 weeks prior to randomization), known positivity for human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg), or anti-hepatitis C virus (HCV) antibodies, a history of alcohol or substance abuse, known hypersensitivity to the investigational products or any of their constituents, pregnancy or lactation during screening or throughout the study period, and individuals classified as vulnerable populations according to the Indian Council of Medical Research (ICMR) guidelines will also be excluded from the study.

Withdrawal criteria

Participants will be withdrawn from the study if they voluntarily withdraw informed consent; exhibit persistent non-compliance or non-adherence to the study protocol or prescribed intervention despite appropriate counselling and reminders; are unwilling or unable to comply with study requirements; are lost to follow-up due to failure to attend scheduled visits or respond to communication attempts for a predefined period; experience a decline in eGFR to <15 ml/min/1.73 m² or require initiation of dialysis; become pregnant during the study period; or develop severe adverse events or treatment-related complications requiring specialized medical care. Such participants requiring specialized medical care will be referred to an appropriate higher healthcare centre for further management.

Follow-up

Participants will be evaluated weekly during the 60-day treatment period and subsequently followed up weekly for 2 weeks after completion of treatment. During these visits, clinical signs and symptoms, vital signs, treatment adherence, adverse events, and quality of life will be assessed to evaluate the sustained treatment response and the safety of the intervention.

Intervention and comparator details

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

Participants in group A will receive Dusparshadi Kashaya orally at a dose of 120 ml twice daily, administered on an empty stomach 30 minutes before breakfast and approximately 5 hours after lunch, along with Chandraprabha Vati (500 mg, two tablets) twice daily after breakfast and dinner with lukewarm water as Anupana. Both interventions will be administered for 60 days in addition to standard medical treatment.

Comparator group (group B)

Participants in Group B will receive standard care alone, comprising antihypertensive, antihyperglycemic, antiemetic, and multivitamin medications, as required according to the stage and clinical condition of the patient, and as advised by the treating physician, for a duration of 60 days.

Procurement, authentication, and preparation of trial drugs

The raw drug Dusparsha for the preparation of Dusparshadi Kwatha (Yawakuta) has been procured from the Ambuja Institute of Ayurveda Research and Documentation (AIARD), Ernakulam, Kerala, India and has been identified and authenticated through pharmacognostical evaluation prior to use. All other

ingredients required for the preparation of Dusparshadi Kwatha and Chandraprabha Vati have been procured from the ITRA Pharmacy, Jamnagar, Gujarat, India. The final formulation of Dusparshadi Kwatha and Chandraprabha Vati has been prepared at the ITRA Pharmacy, Jamnagar, Gujarat, India.

Outcomes

The primary outcome of the study will be improving the eGFR from baseline to 60 days. The secondary outcomes will include a decrease in serum creatinine and serum urea levels, an increase in hemoglobin levels, improvement in quality of life as assessed using the KDQOL™-36 questionnaire, the number of participants requiring the initiation of dialysis, and the number of mortality events occurring during the 60-day study period.

Participant timeline

Table 1 outlines the schedule of events throughout the clinical trial, from screening of the eligible participant to the end of the treatment period. Baseline assessments, including informed consent, demographic data collection, and relevant investigations, will be performed at enrollment. Follow-up visits will be conducted weekly (± 3 days) to assess clinical outcomes, monitor safety, and record any adverse events. Final evaluations will be carried out at the end of the treatment period.

Sample size calculation

The sample size was calculated for a randomized parallel-group clinical trial with a continuous primary outcome. The calculation was performed using a significance level (α) of 0.05 and a statistical power of 80%. An expected mean difference (effect size) of 10 ml/min/1.73 m² in eGFR between the two groups and a standard deviation of 40, derived from previously published clinical studies on Ayurvedic interventions, were considered. The sample size was estimated using the formula:

$$n = \frac{2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2}{\Delta^2}$$

Based on these assumptions, the calculated sample size was 196 participants per group. However, due to financial and logistical constraints, recruitment of the calculated sample size was not feasible. Therefore, a minimum of 15 participants per group was planned for this study.

Allocation

As this is an open-label study, neither the participants nor the investigators will be blinded to the allocated interventions; therefore, allocation concealment and blinding will not be implemented. Although the open-label design may introduce the potential for performance and detection bias, it has been adopted considering the practical and logistical feasibility of the study.

Table 1: The timeline for participants enrolling in trial.

Periods	Screening	Intervention phase								Follow up	
No. of visits	1	2	3	4	5	6	7	8	9	10	11
Visit name	Screening	Randomization								End of intervention period	
Visit window in days	1-7 days	7 days from randomization	7 $\pm$ 3	7 $\pm$ 3	7 $\pm$ 3	7 $\pm$ 3	7 $\pm$ 3	7 $\pm$ 3	7 $\pm$ 3	15 $\pm$ 3	15 $\pm$ 3
Weeks	1-7 days	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th	1 st	2 nd
Informed consent	✓										
Demographics	✓										
Medical history	✓										
Physical exam	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Vital signs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Hematology	✓		✓						✓		
FBS and PPBS			✓						✓		
KFT with eGFR	✓		✓						✓		
Urine routine	✓		✓						✓		
Ferritin	✓		✓						✓		
S. iron and TIBC			✓						✓		
PTH			✓						✓		
Dispense of study drugs		✓	✓	✓	✓	✓	✓	✓	✓		
Adverse reaction			✓	✓	✓	✓	✓	✓	✓		
QoL		✓			✓				✓		✓

Do's and don'ts

Participants will be advised to follow the dietary and lifestyle recommendations specific to Vrikka Roga (CKD) at the time of enrolment and pamphlet will be given to the participants along with the verbal instructions.

Drug and diet compliance

Drug compliance will be ensured and assessed throughout the study period. The trial medications will be administered according to the prescribed dose and treatment schedule. Participants will receive detailed instructions regarding the dosage, frequency, and timing of drug administration. The trial medications will be dispensed at each scheduled follow-up visit, and compliance will be assessed by reviewing the returned medication and participant self report at every visit. All participants will also be advised to adhere to a standardized dietary regimen throughout the study period.

Treatment adherence

Treatment adherence will be assessed through participant interviews, review of medication intake records, and pill counts by counting the unused tablets and coarse powder 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).

Data collection methods

The required data will be collected by the scholar using a case record form, which will include details of presenting symptoms, associated comorbidities, current medications, personal history, vital signs, general physical examination, systemic examinations, Ashtavidha Pariksha, Dashavidha Pariksha, Roga Bala Pariksha, Srotas Pariksha, laboratory investigations, drug compliance, adverse drug reactions, and quality of life assessment using the KDQOL™-36 questionnaire.

Data management

Data from CRF will be entered into pre-specified Excel sheets by the scholar. The data entry will be verified with the double data entry methods. The data of the personal details of the participants will be kept confidential by the scholar.

Statistical analysis

The collected data will be analyzed using appropriate statistical methods and presented as mean, standard deviation (SD), and standard error (SE). Descriptive statistics will be used to summarize demographic and

baseline characteristics. Associations between categorical baseline variables will be assessed using the Chi-square test or Z test, as appropriate. For continuous variables, within-group comparisons will be performed using the paired t test, while between-group comparisons will be analyzed using the unpaired t test. Non-parametric data will be analyzed using the Wilcoxon Signed-Rank Test for within-group comparisons and the Mann-Whitney U test for between-group comparisons. Data will be compiled in Microsoft excel and analyzed using SPSS/Sigma-stat software. Statistical significance will be considered at $p < 0.05$, with $p < 0.01$ indicating high significance and $p < 0.001$ indicating very high significance.

Ethical clearance

Ethical clearance has been obtained (PGT/7-A/Ethics/2026-27/287) and the study has been prospectively registered in CTRI.

Confidentiality

All the trial data recorded will be treated in strict confidence. During documentation and analysis of the trial, the individual participant will be identified only by their enrolment number. The source documents and electronic will be have restricted accessibility.

Trial status

The preparation of trial drug has been completed in month of June, 2026. The recruitment of participants has been initiated.

DISCUSSION

The increasing prevalence of CKD and its progression to end-stage kidney disease continue to pose a major global health challenge. The present study was designed to address an important evidence gap in the integrative management of CKD stages G2-G3b. Early-stage CKD offers a valuable therapeutic window during which timely intervention may delay disease progression; however, evidence supporting Ayurvedic interventions at this stage remains limited. Although Dusparshadi Kashaya and Chandraprabha Vati are traditionally indicated in disorders of the Mutravaha Srotas and possess Mutrala (diuretic), Shothahara (anti-inflammatory), and Rasayana (rejuvenative) properties, their efficacy as adjunctive therapy has not been adequately evaluated in randomized controlled clinical trials. Furthermore, the safety and tolerability of administering Dusparshadi Kashaya at the higher dose (120 mL), as commonly practiced in Sri Lanka, have not been systematically investigated in patients with CKD. Experimental and clinical evidence suggests that several of their phytoconstituents possess antioxidant, anti-inflammatory, and nephroprotective activities that may attenuate the pathological mechanisms underlying CKD progression.⁷⁻¹² By evaluating objective

renal function parameters, including eGFR, serum creatinine, serum urea, and hemoglobin, together with quality of life assessed using the KDQOL™-36 questionnaire, the present study aims to provide a comprehensive assessment of the efficacy and safety of these Ayurvedic formulations as add-on.

Another strength of the present protocol is the evaluation of Dusparshadi Kashaya and Chandraprabha Vati as adjuncts to standard medical management rather than as standalone interventions. This add-on design reflects routine clinical practice and enables assessment of the additional benefits of Ayurvedic therapy without compromising established conventional treatment. The randomized controlled design, standardized outcome measures, and monitoring of drug compliance and adverse drug reactions further strengthen the study methodology. The findings of this study are expected to generate robust clinical evidence regarding the efficacy and safety of these interventions and contribute to strengthening the scientific basis for integrating Ayurveda into the contemporary management of CKD.

CONCLUSION

Dusparshadi Kashaya and Chandraprabhavati are expected to improve eGFR and preserve renal function in participants with CKD stages G2-G3b. The findings of this study may provide evidence for the efficacy and safety of these Ayurvedic formulations as adjunctive therapies in CKD management. If proven effective, this integrative approach could contribute to slowing disease progression, improving quality of life, and reducing the burden of CKD.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee (PGT/7/-A/Ethics/2026-27/287).

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Cite this article as: Alwis TN, Goyal MR. Efficacy of add-on Dusparshadi Kashaya and Chandraprabha Vati in the management of grade 2 to 3b chronic kidney disease: a structured study protocol of open labelled randomized standard controlled clinical trial. *Int J Clin Trials* 2026;13(4):461-6.