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Research Article

COMPARATIVE EFFICACY OF *AMRITADI KWATH* AND *GOKSHURAK RASAYANA* IN THE MANAGEMENT OF CHRONIC KIDNEY DISEASE W. S. R *MUTRAVAHASROTAS DUSHTI*: PROTOCOL OF AN OPEN-LABEL RANDOMIZED CONTROLLED CLINICAL STUDY

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ABSTRACT

Chronic Kidney Disease (CKD) is a major public health concern, particularly in the Indian subcontinent, due to the rising prevalence of diabetes and hypertension. It is characterized by a persistent decline in renal function (eGFR <60ml/min/1.73m^2) or structural kidney damage for more than three months. *Gokshura* (*Tribulus terrestris L*), a key herb in Ayurvedic medicine, has shown favourable outcomes in earlier research related to kidney function support. This study focuses on evaluating the efficacy of *Amritadi Kwath* and *Gokshurak Rasayana* in improving eGFR and overall renal function in CKD patients. **Materials and Methods:** This open-label, randomized controlled clinical trial will include 60 participants aged between 25–65 years diagnosed with CKD stages 1 to 3b as per KDIGO 2021 criteria and exhibiting classical symptoms of *Mutravaha Srotasdusti*. Participants will be randomly allocated using computer-generated randomization into two groups (n=30 each). The trial group will receive *Amritadi Kwath* and the control group will receive *Gokshurak Rasayana* for 30 days, followed by a 30-day observational period. The primary outcome measure will be change in eGFR. Secondary outcome measures will include changes in Sr. creatinine, blood urea, Sr. electrolytes, and clinical symptoms such as *Atishritam Mutram* (Increased frequency of urine), and *Alpa-Alpa Mutra* (oliguria), *Bahalam Mutram (*increase in volume of urine*)*, *Shotha* (edema), *Pandu* (anemia). **Conclusion:** This protocol provides a clinical framework to evaluate Ayurvedic interventions in early-stage CKD and to assess their potential in slowing disease progression and improving patient quality of life.

INTRODUCTION

Chronic Kidney Disease (CKD) is a progressive and irreversible condition affecting kidney structure and function over time. Globally, CKD is recognized as a major public health burden, with an estimated prevalence ranging from 8% to 16% across all stages. Alarmingly, the majority of cases are detected only in advanced stages (G4–G5), often when symptoms become clinically apparent or complications arise. However, a significant proportion of the CKD burden lies in the early stages (1 to 3b), which often remain undiagnosed due to their silent and non-specific presentation. The Kidney Disease Improving Global Outcomes (KDIGO) organization has summarized the stages of CKD using a "traffic light" staging system that incorporates both creatinine-based eGFR and albuminuria. This classification gives five levels of dysfunction defined by eGFR(G1–G5) and three by albuminuria (A1–A3).[1]

Early-stage CKD (Stages 1–3b) is characterized by subtle reductions in kidney function (eGFR ≥30 mL/min/1.73m^2) and/or markers of kidney damage, such as albuminuria, persisting for more than three months. CKD prevalence is increasing in many countries and was the 18th commonest cause of death globally in the Global Burden of Disease Study 2010 (increased from 27th in 1990).[2] According to population-based studies, the prevalence of CKD stage 1 is approximately 3.5%, stage 2 around 3.9%, and stage 3 (including 3a and 3b) accounts for about 7.6%

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of the adult population in various cohorts.[3] In the SEEK (Screening and Early Evaluation of Kidney Disease) India study, the overall prevalence of CKD was reported at 17.2%, with 15.6% of cases falling within stages 1 to 3.[4] These findings highlight that a majority of individuals with CKD fall within stages where timely diagnosis and intervention can significantly delay progression to end-stage renal disease (ESRD).

Despite the asymptomatic nature of early CKD, patients in stages 1 to 3b already exhibit increased cardiovascular risk and metabolic disturbances. Studies have shown that the prevalence of cardiovascular events, hypertension, and diabetes mellitus is significantly higher even in early-stage CKD compared to the general population.[5] Yet, because symptoms are minimal or vague, such as mild fatigue, changes in urination, or generalized weakness, early CKD often goes undetected unless routine screening is conducted.

In Ayurveda, although CKD is not mentioned as a single nosological entity, its clinical features can be understood through the lens of *Mutravaha Srotasdusti* (disorders of the urinary system)- a pathological disturbance in the urinary system. The kidneys (*Vrikka*), considered to be derived from *Rakta* (blood) and *Meda* (fat) *Dhatus*, play a central role in maintaining fluid and metabolic homeostasis, correlating with the excretory and regulatory functions of the renal system. Ayurvedic literature attributes urinary disorders with progressive *Srotasdusti* (channel blockage or dysfunction) of *Rasavaha, Raktavaha, Medovaha*, and *Mutravaha Srotas*.

According to *Acharya Charaka*, the *Basti* (urinary bladder) and *Vankshana* (groin region) are considered the *Mula* (root or origin) of the *Mutravaha Srotas* (urinary system)[6]. Similarly, *Acharya Sushruta* describes that urine is formed in the *Pakvashaya-gata Sthana* (large intestine region) and then carried through the *Gavini* (ureters) to be stored in the *Basti* (urinary bladder)[7]. He further explains that the *Basti* is responsible for regulating *Kleda*- which signifies the maintenance of water and electrolyte balance, comparable to the modern physiological function of the kidneys- and for the collection of urine. This indicates that the formation and excretion of *Mutra* (urine) occur through an integrated chain mechanism involving all components of the *Mutravaha Srotas*. Therefore, any disturbance or pathology affecting any part of this system can lead to *Mutravaha Srotas Dushti* (disorders of the urinary system).

The classical formulations *Amritadi Kwath*[8] and *Gokshurak Rasayana*[9] have been traditionally used in managing disorders of the urinary tract. *Amritadi Kwath* is known for its anti-inflammatory, antioxidant, diuretic and immunomodulatory properties, while *Gokshurak Rasayana*, rich in *Gokshura* (*Tribulus terrestris*), is recognized for its diuretic and renal-supportive actions. These formulations may offer therapeutic benefit in early-stage CKD by reducing symptom burden, improving renal parameters, and slowing disease progression. The details of the ingredients of these formulations with their properties have been provided as Table 1and Table 2.

This study focuses on the clinical evaluation of *Amritadi Kwath* and *Gokshurak Rasayana* in CKD stages 1 to 3b, with the objective of demonstrating their role in early intervention. By identifying CKD in its initial phases and initiating Ayurvedic management, this approach aims to delay disease progression and reduce the risk of long-term complications.

Table 1: Ingredients of *Amritadi kwath* with their properties

S.No	Ingredients	*Rasa*	*Guna*	*Virya*	*Vīpaka*	*Karma*
1.	*Amrita (Tinospora cordifolia* wild)	*Tikta, Kashaya, Katu*	*Laghu, Guru, Snigdha*	*Ushna*	*Madhura*	*Rasayana, Balya, Agni Deepana, Tridoshshamaka, Dahanashak, Pandunashaka*
2.	*Nagar (Zingiber officinale* Rosc.)	*Katu*	*Laghu, Snigdha*	*Ushna*	*Madhura*	*Dipaniya, Shothagana, Shleshmahara,*
3.	*Vajigandha [Withania somnifera* (L.) Dunal]	*Tikita, Madhura, Kashaya*	*Laghu, Snigdha*	*Ushna*	*Madhura*	*Rasayana, Pramehaghna, Dahahara, Medohara, Shophaghna, Dahaprashamana*
4.	*Dhatri (Emblica officinalis* Geartn.)	*Amla, Kashaya, Tikta, Katu, Madhur*	*Guru, Ruksha, Sheeta*	*Sheeta*	*Madhura*	*Shothahara, Vedanasthapana, Deepana, Mutrala Anulomana, Raktashodhaka, Kaphaghna, Rasayana*

5.	*Trikantak (Tribulus terrestris* L.)	*Madhura*	*Guru, Snigdha*	*Sheeta*	*Madhura*	*Mutravirechaniya, Shothahara, Vatahara, Bala-krut, Basti-Shodhana, Dipana, Ashmarihara, Pramehahara, Mutrakricchahara*

Table 2: Ingredients of *Gokshurak Rasayana* with their Properties

1.	*Gokshura (Tribulus terrestris* L.)	*Madhura*	*Guru, Snigdha*	*Sheeta*	*Madhura*	*Mutravirechaniya, Shothahara, Vatahara, Bala-krut, Basti-Shodhana, Dipana, Ashmarihara, Pramehahara, Mutrakricchahara*

MATERIALS AND METHODS

Study design

This study will be an open label randomized controlled trial. This trial aims to compare the efficacy of *Amritadi kwath* (containing *Amrita, Nagar, Ashwagandha, Dhatri* with *Gokshur*) and *Gokshurak Rasayana.*

Randomization

Participants meeting the inclusion criteria will be randomly allocated into two groups- Group A and Group B- using a computer-generated simple randomization technique to ensure objective and unbiased group assignment. Group A will receive *Amritadi Kwath*, while Group B will be administered *Gokshurak Rasayana*. The use of a computerized randomization method enhances the methodological rigor of the study by reducing selection bias and ensuring equal distribution of participants across both intervention arms.

Study Setting

The participants for this study will be screened and enrolled from both the Outpatient and Inpatient Departments of Chaudhary Brahm Prakash Ayurved Charak Sansthan (CBPACS), Khera Dabar, Najafgarh, New Delhi.

Sample Size

The sample size was calculated using the online sample size calculator available at OpenEpi.com, considering e-GFR as the primary continuous outcome variable. A total of 60 patients will be enrolled in the study, with 30 participants in each group. The calculation was based on 80% statistical power and a 95% confidence interval, with an anticipated dropout rate of 10% already accounted for. The sample size determination was informed by data from a previously published clinical study on Ayurvedic management of chronic kidney disease.

Eligibility criteria and enrolment

Participants will be diagnosed with chronic kidney disease (CKD) using a precise operational case definition. Those who fulfil all inclusion criteria and do not meet any exclusion criteria will confidently be considered eligible to participate in the study, provided they give their written informed consent.

Using both Ayurvedic and contemporary diagnostic techniques, we will collect baseline data at enrolment, such as demographics and clinical history. A structured case record form (CRF) will be employed to thoroughly document the patients' initial status and effectively track their progress throughout the study.

Inclusion criteria

This study will include patients clinically diagnosed with Chronic Kidney Disease (CKD) of stages 1, 2, 3a, or 3b, with or without anemia, in accordance with the KDIGO (Kidney Disease: Improving Global Outcomes) guidelines. Eligible participants must exhibit a minimum of three classical symptoms indicative of *Mutravaha Srotas Dushti*, along with features suggestive of *Pandu* as described in Ayurvedic texts. Patients with well-controlled Type 2 Diabetes Mellitus (defined as FBS ≤ 130mg/dl, PPBS ≤ 200mg/dl, and HbA1c < 9%) presenting with CKD symptoms, with or without associated hypertension or diabetes, will be considered. The study will enrol both male and female subjects aged between 25 and 65 years who are willing to provide written informed consent and are not currently participating in any other clinical or research study. Furthermore, only patients with CKD attributable to prerenal or intrinsic renal causes will be included in the trial.

Exclusion criteria

Patients will be excluded from the study if they are on insulin therapy for glycaemic control. Individuals with Stage 4 hypertension, defined as blood pressure ≥160/100 mmHg despite ongoing antihypertensive medication, will also be excluded. Patients currently undergoing dialysis or those who have received a renal transplant will not be eligible. The study will exclude individuals with urinary tract obstructions such as benign prostatic hyperplasia (BPH), renal calculi, or renal tumor, as well as those diagnosed with chronic infectious diseases including HIV, Hepatitis B, or Hepatitis C. Pregnant or lactating women will not be included in the trial. Additionally, patients with severe systemic conditions such as coronary artery disease (CAD), malignancy, chronic liver disease, ascites, tuberculosis, or sexually transmitted diseases will be excluded to minimize

confounding factors and ensure safety during the study.

Withdrawal criteria

Participants will be withdrawn from the study under the following circumstances: the occurrence of any serious adverse events that may compromise patient safety or necessitate immediate medical attention; a significant clinical deterioration observed during the intervention period, indicating a lack of therapeutic benefit or worsening of disease status; and any marked elevation in blood pressure or blood glucose levels beyond the predefined inclusion limits (i.e., uncontrolled hypertension or hyperglycaemia). In such cases, the intervention will be discontinued in the best interest of the patient's health, and appropriate medical care will be provided as required.

Drug Intervention

Participants will be randomly assigned to one of two intervention groups. Group A will receive *Amritadi Kwath* at a dose of 40ml twice daily- once in the morning on an empty stomach and once in the evening, two hours before meals (*Apana kala*). Group B will receive *Gokshura Rasayana*, 5 grams twice daily after meals, administered with *Godugdha* (100ml) as *Anupana*. The total duration of intervention for both groups will be 30 days. Follow-up assessments will be conducted twice- on the 45th and 60th day of treatment. Patients who are already on medications for other chronic conditions such as hypertension or diabetes will continue their prescribed treatments as concomitant medication throughout the study period, without interruption. The Ayurvedic formulations used in this study will be procured from *Anavarin* Ayurveda, a certified manufacturer, to ensure the highest standards of quality, authenticity, and consistency throughout the trial.

Outcome Measures

The primary outcome of the study will be the improvement in Estimated Glomerular Filtration Rate (e-GFR), calculated using standard laboratory values to assess renal function. Secondary outcomes will include a reduction in serum creatinine and blood urea levels, correction of electrolyte imbalances (sodium, potassium, calcium, phosphate, and bicarbonate), and an increase in hemoglobin percentage (Hb%). Additionally, clinical evaluation will focus on the improvement in the severity of symptoms related to *Mutravaha Srotas Dushti*, including altered urinary patterns such as *Atisrishtam, Atibaddha Mutram, Alpa-Alpa Mutra* (e.g., increased frequency, anuria, or oliguria), and *Bahalam Mutram* (Increase in volume of urine). Systemic symptoms such as muscle cramps, anorexia, generalized weakness, fatigue, *Akshikuta-Mukha-Paade Shotha* (facial and pedal edema), *Raktalpata* and *Pandutvam* (features of anemia), and *Alpamedat*a (progressive weight loss) will also be recorded and analysed. These outcome measures aim to comprehensively evaluate the therapeutic impact of the interventions from both biomedical and Ayurvedic perspectives.

Frequency of Data Collection and Assessments

Data will be collected at predefined intervals throughout the study duration to ensure consistent monitoring of treatment outcomes. Baseline data will be recorded at the time of patient enrolment and initiation of therapy. Follow-up assessments will be conducted at regular intervals- specifically on day 1, day 9, day 16, day 23, day 30, day 45, and day 60- as outlined in the study protocol. At each visit, comprehensive clinical evaluations will be performed, including measurements of blood pressure, body weight, and symptom assessment based on *Mutravaha Srotas Dushti*. In addition, laboratory investigations such as serum creatinine, blood urea, serum electrolytes (Na^+, K^+, Ca^{2+}, PO_4^{3-}, HCO_3^-), haemoglobin percentage, fasting and postprandial blood glucose levels, and calculated e-GFR will be carried out. This structured assessment schedule allows for both objective and subjective evaluation of therapeutic response over time. The layout of the assessment of the study is shown in Table 3.

Table 3: Gantt Chart of the study

Steps	Day 0	Day 1	Day 2-8	Day 9	Day 9-15	Day 16th	Day 16-22nd	Day 23rd	Day 23-30th	Day 30th	Day 45th	Day 60th
Screening	✓											
History & Physical Examination	✓											
Patient Enrolment Sign consent		✓										
Drug Intervention			Day 2-30TH									

Assessment of symptoms	✓			✓		✓		✓		✓	✓	✓
eGFR	✓	✓		✓		✓		✓		✓	✓	✓
Sr. Creatinine Sr. Blood Urea Sr. Electrolytes	✓	✓		✓		✓		✓		✓	✓	✓
Hb% FBS&PPBS	✓	✓		✓		✓		✓		✓	✓	✓
B.P. Weight	✓	✓		✓		✓		✓		✓	✓	✓
Follow Up				✓		✓		✓		✓	✓	✓

Data Collection

Data will be collected using predesigned physical proformas for subject screening, medical history, and clinical evaluation. All collected data will be subsequently digitized and entered into structured Excel spreadsheets. Two digital copies will be maintained: one retained by the principal investigator for ongoing analysis and monitoring, and the second securely submitted to the department for archival and future reference. This dual-record system ensures accuracy, transparency, and traceability throughout the study.

Data Management

Only data from participants who complete at least 80% of the scheduled follow-up assessments will be included in the final analysis to ensure data reliability and consistency. Reasons for participant dropout will be documented systematically using a separate predefined proforma. This approach will help account for missing data, maintain transparency, and support the integrity of the study findings.

Data Analysis

All statistical analyses will be performed after the completion of the clinical trial to assess and compare the efficacy of interventions in the two study groups. Data will be subjected to appropriate statistical tests, including paired t-test for within-group comparisons, unpaired t-test for between-group comparisons, and one-way ANOVA where applicable. These methods will help determine the significance of observed changes in both clinical and laboratory parameters. A p-value of <0.05 will be considered statistically significant, indicating a meaningful therapeutic effect, whereas a p-value >0.05 will be regarded as statistically non-significant. All data will be critically evaluated to ensure the validity and reliability of the study findings.

Ethics

Research Ethics Approval

This clinical study will be conducted following established ethical guidelines. The complete study protocol, including informed consent documents and supporting materials, was reviewed and approved by the Institutional Ethics Committee (IEC) of Chaudhary Brahm Prakash Ayurved Charak Sansthan, Najafgarh, New Delhi. Ethical clearance was granted under the reference number CBPACS/Prin/IEC/3719-20, dated 13-09-2024. Additionally, the study has been prospectively registered with the Clinical Trials Registry of India (CTRI) to ensure transparency and adherence to regulatory standards.

Protocol Amendments

Any important changes made to the study protocol- such as modifications in eligibility criteria, outcome measures, analytical methods, or other key components- will be promptly reported to the Institutional Ethics Committee (IEC), registered in the trial registry, and communicated to all study participants.

Informed Consent

Written informed consent will be obtained from every participant by the primary investigator. Participants will receive detailed information regarding the purpose of the study, procedures involved, possible risks, and expected benefits. Participation will be entirely voluntary, and individuals will be given sufficient time to ask questions and make an informed decision.

Confidentiality

All personal information of both potential and enrolled participants will be handled with strict confidentiality. Unique identification codes will be used in place of personal identifiers, and all data will be securely stored. Access to this information will be

limited to authorized research personnel only, ensuring privacy is maintained throughout the study.

Ancillary and Post-Trial Care

Participants will receive appropriate supportive care in case they develop any health concerns during the study period. After completion of the trial, participants will be followed up for a period of four weeks to assess their health status. Additional referrals or continued treatment will be arranged as required, ensuring their well-being is maintained even after the study concludes.

DISCUSSION

Chronic Kidney Disease (CKD) is a progressive and irreversible disorder that significantly compromises renal function, leading to disruptions in fluid, electrolyte, and metabolic regulation. It has become a pressing global health issue, with its prevalence steadily rising due to the growing burden of lifestyle-related conditions such as type 2 diabetes mellitus and hypertension. These chronic diseases contribute to long-term nephron damage, ultimately resulting in reduced filtration capacity and systemic complications including cardiovascular disease, anemia, and mineral-bone disorders.

One of the primary challenges in CKD management is its silent progression in the early stages. Symptoms often remain unnoticed until substantial renal function has been lost. This makes early detection crucial, as timely intervention can slow progression, preserve kidney function, and reduce long-term complications. Routine assessment of parameters such as e-GFR, serum creatinine, blood urea, and urine output plays a vital role in monitoring disease status and guiding therapy.

Standard modern treatments focus on managing underlying causes and delaying disease progression through the use of pharmacological agents like ACE inhibitors and ARBs. While effective, these treatments are not curative and may not be accessible or sustainable for all patients- particularly in regions with limited healthcare infrastructure. As CKD contributes heavily to global morbidity, mortality, and healthcare expenditure, there is a strong public health need to explore alternative, cost-effective, and preventive strategies.

In this context, Ayurveda offers a promising complementary approach. Preliminary clinical observations and case studies indicate that Ayurvedic interventions may help reduce serum creatinine levels, improve urine output, manage symptoms such as edema and fatigue, and enhance overall well-being. Formulations with *Rasayana* (rejuvenating), *Mutrala* (diuretic), and *Srotoshodhaka* (channel-cleansing) properties are traditionally used in the management of urinary and renal disorders. These therapies focus on strengthening bodily systems, addressing the root cause of disease, and promoting long-term systemic balance.

Importantly, this study adopts a randomized controlled trial design, which strengthens the credibility of findings by reducing selection bias and allowing for objective comparison between treatment groups. Scientific validation of Ayurvedic therapies through such rigorous methodologies is essential to bridge traditional knowledge with modern clinical evidence. If proven effective, Ayurveda could offer an accessible, culturally accepted, and economically viable model for early-stage CKD management and prevention- particularly in regions where modern nephrology services are limited.

In summary, integrating early diagnosis with evidence-informed Ayurvedic interventions has the potential to improve patient outcomes, delay the need for renal replacement therapies, and reduce the overall burden of CKD. This highlights the importance of exploring integrative, preventive healthcare strategies in the face of rising chronic disease challenges.

CONCLUSION

This protocol outlines a clinical study evaluating the effectiveness of Ayurvedic interventions in the early to moderate stages of CKD (*Mutravahasrotas Dushti)*. The study anticipates improvement in renal function parameters and associated clinical symptoms, thereby providing evidence for the supportive and complementary role of Ayurveda in slowing disease progression and enhancing overall outcomes in CKD management.

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