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Research Article

Renal calculi

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A Prospective, Open-label Non-Randomized Clinical Trial to evaluate the Safety and Efficacy of Calcury Tablets in Treatment of Renal calculi

Mote D[1], Chaudhari N[2*], Maurya MN[3]

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[1] Dnyaneshwar Mote, Principal Investigator, Vidnyanam Clinic, Katraj-Kondhwa Road, Katraj, Pune, Maharashtra, India.
[2*] Nikhil Chaudhari, Co-Investigator and Consultant Physician, Chaudhari Clinic, Kamothe, Panvel, Navi Mumbai, Maharashtra, India.
[3] Manasi N Maurya, Medical Advisor, Charak Pharma Pvt Ltd Mumbai, Maharashtra, India.

Background: Renal calculi, commonly referred to as kidney stones, are a prevalent urological condition characterized by the formation of solid mineral and salt deposits within the urinary tract. The management of renal stones involves a multifaceted approach, including hydration, dietary modifications, pain management, pharmacological interventions, and, in some cases, surgical procedures such as lithotripsy or ureteroscopy. Preventive strategies focus on addressing the underlying metabolic causes and promoting adequate hydration to minimize recurrence.

Materials and Methods: This non-randomized, prospective, open-label clinical trial involving 50 patients aimed to evaluate the clinical efficacy and safety of Calcury Tablets in managing renal calculi in patients aged 20–65 years, a demographic representative of the global population commonly affected by kidney stones.

Study Design: Participants were thoroughly informed about the study procedures, and written consent was obtained before enrollment. The study followed participants over a 4 weeks period to monitor treatment efficacy and safety. Assessments were conducted before and after treatment to evaluate changes in stone size, symptom relief, and recurrence prevention. Any adverse events or complications were carefully documented and analyzed.

Observations and Results: This clinical trial evaluated the safety and efficacy of Calcury Tablets in managing renal stones in 50 participants (mean age: 47.3 years; BMI: 27.2). Significant reductions were observed in stone size (6.5 ± 1.8 mm to 4.0 ± 1.2 mm, p = 0.001), stone number (3.5 ± 1.4 to 2.1 ± 1.0, p= 0.01), and pain levels (VAS: 6.5 ± 2.0 to 3.2 ± 1.4, p= 0.001). Stone passage increased from 60% to 90% (p = 0.03), and urine pH improved from 5.8 ± 0.6 to 6.3 ± 0.5 (p = 0.05). Quality-of-life scores rose significantly (48.2 ± 8.5 to 65.1 ± 7.2, p = 0.001), alongside hydration improvements (2.0 ± 0.5 to 2.5 ± 0.6 L/day, p = 0.04). Laboratory parameters remained stable, indicating safety, with no significant impact on renal, hepatic, or hematological markers.

Conclusion: The clinical evidence from this trial, combined with the promising previous studies on the individual herbs involved in the formulation, supports the use of Calcury Tablets as an effective, safe, and natural alternative for managing renal stones. This treatment offers a promising option for patients seeking a holistic approach compared to conventional medications.

Keywords: Calcury Tablet, Renal calculi, Kidney stones, Nephrolithiasis, Urolithiasis, Urinary tract obstruction

Corresponding Author

Nikhil Chaudhari, Co-Investigator and Consultant Physician, Chaudhari Clinic, Kamothe, Panvel, Navi Mumbai, Maharashtra, India.
Email: regulatory@charak.com

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Introduction

Renal calculi, or kidney stones, are crystalline formations in the urinary tract caused by the supersaturation of minerals in urine, affecting 10-15% of people in developed countries. They can cause severe pain, hematuria, and urinary obstruction, often requiring treatments like medication, extracorporeal shock wave lithotripsy (ESWL), or surgery.

Stones are classified by composition, with common types including calcium oxalate, calcium phosphate, uric acid, struvite, and cystine. Formation is influenced by genetic, dietary, metabolic, and environmental factors, with recurrence being a frequent issue. Improved imaging techniques, such as ultrasonography and CT, aid detection, but challenges remain in reducing recurrence and treatment complications.**[1]**

Epidemiology: Renal calculi, or kidney stones, affect 5–15% of people worldwide, influenced by factors such as age, location, and lifestyle. In Asia, 1%-19.1% of the population experiences urolithiasis, primarily among individuals aged 30–60, with men more commonly affected, though the gender gap is narrowing. Stones recur in 21%-53% of cases within 3-5 years. Calcium oxalate (75%-90%) is the most common type, followed by uric acid, calcium phosphate, struvite, apatite, and cystine. Risk factors include genetics, metabolic issues, diet, dehydration, and conditions like obesity and diabetes. Western diets, low fluid intake, hot climates, and metabolic syndrome also contribute to stone formation.**[2]**

Symptomatology: The symptoms of calculous nephritis and urethritis vary with the size, location, and movement of renal stones. Small stones may cause mild lumbar pain, microscopic hematuria, and occasional albuminuria, often misdiagnosed as chronic nephritis. Larger stones, especially in the renal pelvis, typically result in flank pain, hematuria, and intermittent colic. Stones lodged in the ureter can cause severe renal colic, sharp pain radiating to the groin, nausea, vomiting, and, if untreated, hydronephrosis or unilateral anuria. Infections may lead to pyonephrosis or calculous pyelitis, with fever, malaise, and abdominal tenderness, resembling other conditions like appendicitis. Changes in urine pH from infections can worsen stone formation.

Urinalysis detects hematuria, albuminuria, and pyuria, while imaging (CT, ultrasound, X-rays) is essential for identifying stone size, location, and complications. Early diagnosis through imaging is crucial to prevent further renal damage or chronic kidney disease.**[3]**

Pathogenesis: The pathogenesis of urolithiasis involves crystal nucleation, growth, aggregation, and retention in the urinary tract, driven by physicochemical urine changes, anatomical variations, and metabolic abnormalities. Stone formation begins with urine supersaturation with salts like calcium, oxalate, phosphate, uric acid, or cysteine. Low urine volume and altered pH influence supersaturation, with high pH favoring calcium phosphate stones and low pH promoting uric acid stones.

Crystal nucleation follows supersaturation, where ions aggregate to form seeds. Nucleation may occur spontaneously or around surfaces like Randall's plaques or damaged cells. Crystals grow and aggregate under the influence of stone promoters (e.g., oxalate, uric acid) and inhibitors (e.g., citrate, magnesium). Retention mechanisms, including the fixed-particle and free-particle theories, explain how crystals persist in the urinary tract. Randall's plaques and intraluminal plugs act as anchors for stone formation. The balance between promoters and inhibitors is critical. Excess promoters or deficient inhibitors increase stone risk. Contributing factors include metabolic abnormalities (e.g., hypercalciuria, hyperoxaluria), anatomical conditions (e.g., medullary sponge kidney), and urease-producing infections, which can promote specific stone types.**[4]**

Conventional Treatment: Various pharmacological therapies are tailored to treat different types of renal calculi. Calcium oxalate stones are primarily managed with thiazide diuretics, reducing recurrence rates by up to 70%, particularly in idiopathic hypercalciuria, while citrate supplements help prevent stone formation. Pyridoxine may aid hyperoxaluria, though clinical benefits of oxalate-degrading bacteria like *Oxalobacter formigenes* remain inconclusive. Uric acid stones are treated with alkali therapy to enhance solubility and allopurinol to lower uric acid levels. For struvite stones, antibiotics are standard, with acetohydroxamic acid occasionally used to inhibit urease-producing bacteria.

Cystine stones require high fluid intake, urine alkalinization, and chelating agents like D-penicillamine or tiopronin for severe cases.[5] Medical expulsive therapy (MET) helps pass ureteric stones, particularly those <5 mm, using alpha-blockers (e.g., tamsulosin), calcium channel blockers (e.g., nifedipine), corticosteroids, and hydration. Tamsulosin with corticosteroids is notably effective, reducing expulsion time and analgesic use. If stones persist beyond four weeks, urological intervention is necessary to prevent complications. Herbal alternatives are gaining attention, but existing therapies have side effects requiring monitoring. Thiazides can cause hypokalemia, hyponatremia, and gout, while citrate supplements may cause gastrointestinal discomfort. Pyridoxine is useful for primary hyperoxaluria but may cause nerve toxicity at high doses. Allopurinol for uric acid stones may lead to skin rashes or rare severe reactions. Chelating agents for cystine stones, D-penicillamine and tiopronin, can induce nausea and renal toxicity. MET agents like tamsulosin and nifedipine are effective but may cause dizziness, hypotension, or retrograde ejaculation. Monitoring is essential to balance benefits and risks.[6,7] In present study, Calcury Tablets, a polyherbal formulation, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patie. with renal calculi. Formulation has been stand-ardized after formulating SOPs along with acute toxicity study. A total of 50 patients were studied.

Aim and Objectives

The main objective of the study was to evaluate clinical efficacy of Calcury Tablets in renal calculi. Further, the study also observed clinical safety of Calcury Tablets on renal calculi.

Materials and Methods

Study Design: A non-randomized, prospective open label clinical trial in subjects diagnosed with renal calculi was planned following required GCP guidelines. A total of 50 participants were included in the study diagnosed with renal calculi.

Inclusion Criteria

The trial included men and women aged 20–65 years with a confirmed diagnosis of primary renal calculi, determined through clinical evaluation and imaging studies (e.g., ultrasound or CT scan). Participants had a history of recurrent renal stones, moderate to severe symptoms associated with renal calculi (such as pain, hematuria, or hydronephrosis), or evidence of a previous stone episode. Candidates were in generally good health, without significant uncontrolled comorbidities, such as severe cardiovascular, hepatic, or renal dysfunction, that could have interfered with study participation. Eligible participants provided informed consent and adhered to the study's requirements, including regular visits, compliance with the treatment regimen, and monitoring protocols. They demonstrated the ability to understand and communicate study-related information effectively with the research staff. Additionally, participants were able to attend study visits and complete the trial as planned. These inclusion criteria ensured a diverse participant pool while maintaining safety and reliability in evaluating the treatment's efficacy and safety for renal calculi.

Exclusion Criteria

The exclusion criteria for the clinical trial focused on participants who were at risk for adverse effects or factors that could interfere with the study's validity. Women who were pregnant or breastfeeding, as well as those with severe comorbid conditions such as uncontrolled heart failure, renal or liver disease, or other major systemic illnesses, were excluded. Participants who had undergone major urological surgeries, such as nephrectomy, were also excluded to avoid confounding the results. Individuals with a known allergy or hypersensitivity to the study medication, active urinary tract infections, or a history of urological malignancy were not eligible. Additionally, participants involved in other clinical trials, those with significant psychiatric disorders, or individuals unlikely to comply with study protocols due to cognitive or communication impairments were excluded. Lastly, participants receiving treatments for kidney stone prevention were not included to avoid interactions with the investigational treatment. These criteria ensured participant safety and preserved the integrity of the trial.

Blood tests were conducted to measure renal function. Urinalysis was performed to assess parameters like urinary pH, calcium, and oxalate levels. Urological evaluations were conducted through imaging studies, such as ultrasonography and/or X-rays.

The primary outcome of the trial was to assess the efficacy of Calcury Tablets in reducing the size or number of renal stones, while secondary outcomes focused on evaluating safety through the monitoring of adverse events. All data were documented in the CRF, and any adverse events were closely monitored throughout the 4 weeks study duration.

The investigator recorded the severity and relationship of any adverse events to the study medication. The study was conducted in accordance with Good Clinical Practice (GCP) guidelines to ensure participant safety and data integrity.

Clinical assessments

In this clinical assessment for the use of Calcury Tablets in patients with renal stones, patients were evaluated at baseline and after 4 weeks' treatment period. The primary measure of efficacy was the reduction in the size and number of renal stones, assessed through imaging studies such as ultrasounds and/or X-rays. Stone passage and retention were also monitored, particularly for smaller stones (under 5 mm), with a focus on evaluating the need for any surgical intervention in cases of larger stones.

Pain and discomfort were evaluated using a standardized scale, such as the Visual Analog Scale (VAS), to record symptoms like flank pain, colic, and burning or discomfort during urination. In addition, necessary laboratory investigations were conducted both before the start of treatment and after completion of the 4 weeks period.

These included blood tests to monitor renal function (serum creatinine, blood urea nitrogen [BUN], and electrolytes), as well as urinalysis to assess calcium, oxalate, and urine pH levels. Adequate hydration and fluid intake were also monitored, as they are crucial for the dissolution and passage of stones.

Quality of life was an essential aspect of this assessment, with improvements in physical well-being, daily activities, and emotional state (e.g., stress or anxiety related to renal stones) measured using standard questionnaires. Patients were asked about their satisfaction with the treatment, including any perceived effectiveness and the presence of any side effects. Overall, this study aimed to evaluate the safety and efficacy of Calcury Tablets in reducing stone size, alleviating pain, and improving renal health over the 3-month treatment period.

Intervention

Calcury Tablets, containing *Pashanbheda, Punarnava, Varuna* & *Gokshura*; manufactured by Charak Pharma Pvt. Ltd., was evaluated for its efficacy and safety in patients with renal stones.

The treatment regimen consisted of two Tablets taken twice daily after meals with water. Patients were instructed to maintain adequate hydration throughout the study period. The treatment continued for 4 weeks, with assessments at baseline and after the treatment period.

Key evaluation parameters included the size and passage of renal stones, pain relief, and renal function monitored through imaging and laboratory tests such as serum creatinine and urine pH. Patient satisfaction, side effects, and improvements in quality of life were also recorded.

Observations

Table 1. Shows demographic data of participants. Table 2: Shows Clinical assessment parameters for efficacy of Calcury Tablets. Table 3: Shows Clinical parameters for safety of Calcury Tablets.

Table 1: Demographic data of the participants

Parameter		Mean	Standard Deviation (SD)
Age (years)		47.3	7.9
Weight (kg)		77.2	7.7
Height (cm)		169.2	7.5
BMI		27.2	2.0
Gender	Male	30	-
	Female	20	
Diabetes	Yes	31	-
	No	19	
Hypertension	Yes	27	-
	No	23	
Stone Types	Calcium Oxalate	18	-
	Uric Acid	12	-
	Struvite	10	-
	Cystine	6	-
Previous Stone Episodes		2.4	1.1
Treatment History	Previous Surgery	15 (30%)	-
	Previous Medication	25 (50%)	-

Table 2: Clinical assessment Parameters for efficacy of Calcury Tablets

SN	Parameter		Before treatment (Mean ± SD)	After treatment (Mean ± SD)	p-value
1.	Renal Stone Size (mm)		6.5 ± 1.8	4.0 ± 1.2	0.001
2.	Number of Stones		3.5 ± 1.4	2.1 ± 1.0	0.01
3.	Stone Passage (Yes/No)		60% (Yes)	90% (Yes)	0.03
4.	Pain (VAS score)		6.5 ± 2.0	3.2 ± 1.4	0.001
5.	Flank Pain Frequency		5.2 ± 1.3	2.0 ± 1.0	0.04
6.	Urination Discomfort (VAS)		5.8 ± 1.5	3.0 ± 1.2	0.03
7.	Urine pH		5.8 ± 0.6	6.3 ± 0.5	0.05
8.	Electrolytes	Sodium	137.5 ± 4.0	138.2 ± 3.5	0.15
		Potassium	4.2 ± 0.5	4.1 ± 0.4	
		Calcium	9.3 ± 0.4	9.4 ± 0.3	
9.	Urinary Calcium (mg/dL)		120.5 ± 40.3	105.2 ± 35.6	0.04
10.	Urinary Oxalate (mg/dL)		35.2 ± 10.8	30.1 ± 8.5	0.05
11.	Hydration Status (mL/day)		2.0 ± 0.5	2.5 ± 0.6	0.04
12.	Quality of Life (Scale)		48.2 ± 8.5	65.1 ± 7.2	0.001
13.	Treatment Satisfaction (VAS)		3.9 ± 1.0	6.8 ± 1.2	0.002

Table 3: Clinical Parameters for Safety of Calcury Tablets

Laboratory Test		Baseline	After Treatment	Significant Changes
Hemoglobin (g/dL)		14.5	14.3	No
White Blood Cell Count (cells/μL)		6,500	6,900	No
Platelet Count (cells/μL)		250,000	255,000	No
Liver Enzymes	ALT (U/L)	25	27	No
	AST (U/L)	22	23	
Creatinine (mg/dL)		0.9	1.0	No
Blood Urea Nitrogen (mg/dL)		15	14	No
Electrolytes (mEq/L)	Sodium	140	139	No
	Potassium	4.1	4.0	
	Chloride	102	101	
Fasting Glucose (mg/dL)		85	90	No
Total Bilirubin (mg/dL)		0.8	0.8	No
Albumin (g/dL)		4.1	4.0	No

Results

This clinical trial on Calcury Tablets involved total of 50 participants, with mean age of 47.3 years (SD = 7.9), mean weight of 77.2 kg (SD = 7.7), & an average height of 169.2 cm (SD = 7.5). participants had mean BMI of 27.2 (SD = 2.0), indicating slightly overweight population. Among participants, 30 were male & 20 were female. In terms of medical conditions, 31 participants had diabetes, while 19 did not, & 27 had hypertension, with 23 participants not suffering from this condition.

Regarding the types of stones, the participants had a variety of stone types, including Calcium Oxalate (18), Uric Acid (12), Struvite (10), and Cystine (6). On average, participants had experienced 2.4 previous stone episodes (SD = 1.1). Treatment history revealed that 15 participants (30%) had undergone previous surgery, while 25 participants (50%) had received prior medication for stone management. This demographic profile provides insight into the clinical characteristics of the trial population and sets the stage for evaluating the effectiveness of Calcury Tablets in this cohort.

Calcury Tablets demonstrated significant reductions in renal stone size (from 6.5 ± 1.8 mm to 4.0 ± 1.2 mm, p=0.001) and the number of stones (from 3.5 ± 1.4 to 2.1 ± 1.0, p=0.01) were observed, indicating the Tablets 's effectiveness in reducing stone burden. Additionally, the passage of stones increased from 60% to 90% (p=0.03). Pain levels, assessed via Visual Analogue Scale (VAS), showed a significant decrease in both overall pain (from 6.5 ± 2.0 to 3.2 ± 1.4, p=0.001) and flank pain frequency (from 5.2 ± 1.3 to 2.0 ± 1.0, p=0.04), along with a reduction in urination discomfort (from 5.8 ± 1.5 to 3.0 ± 1.2, p=0.03). Urine pH increased slightly from 5.8 ± 0.6 to 6.3 ± 0.5 (p=0.05), suggesting improved urinary conditions. Urinary calcium and oxalate levels also decreased (p=0.04 and p=0.05, respectively). Hydration status improved, with daily intake increasing from 2.0 ± 0.5 to 2.5 ± 0.6 litres (p=0.04). Additionally, the quality-of-life scores increased significantly (from 48.2 ± 8.5 to 65.1 ± 7.2, p=0.001), and treatment satisfaction improved, as reflected by a rise in VAS score from 3.9 ± 1.0 to 6.8 ± 1.2 (p=0.002). Overall, Calcury Tablets demonstrated a substantial positive impact on stone reduction, pain relief, and overall patient well-being, with most clinical parameters showing significant improvements. The clinical trial report of Calcury Tablets evaluated various laboratory tests to assess the safety and physiological effects of the treatment. Hemoglobin levels remained stable, with no significant changes (14.5 g/dL at baseline vs. 14.3 g/dL post-treatment), indicating no adverse effects on red blood cell production. White blood cell count showed a slight increase from 6,500 cells/μL to 6,900 cells/μL, but this change was not significant and remained within normal limits. Platelet count remained stable at 250,000 cells/μL at baseline and 255,000 cells/μL after treatment, indicating no impact on platelet production.

Liver enzyme levels (ALT and AST) showed minor fluctuations but remained within normal ranges, indicating no liver dysfunction. Creatinine and blood urea nitrogen (BUN) levels, indicators of renal function, were stable, with creatinine rising slightly from 0.9 mg/dL to 1.0 mg/dL and BUN dropping from 15 mg/dL to 14 mg/dL. Electrolyte levels, including sodium, potassium, and chloride, remained balanced throughout the treatment period. Fasting glucose levels were stable, with a minor increase from 85 mg/dL to 90 mg/dL. Total bilirubin and albumin levels also remained unchanged, suggesting no significant effect on liver function or protein synthesis. Overall, the results indicate that Calcury Tablets had no significant impact on the various laboratory parameters measured, supporting the treatment's safety and stability.

In conclusion, the clinical trial of Calcury Tablets demonstrated significant therapeutic benefits in the management of renal stones. The treatment resulted in substantial reductions in both the size and number of stones, as well as an increased rate of stone passage. Participants also reported notable improvements in pain relief, with decreases in overall pain, flank pain, and urination discomfort. The treatment contributed to enhanced hydration, improved urinary conditions, and a positive shift in quality-of-life scores, reflecting an overall improvement in patient well-being. Additionally, laboratory tests indicated that Calcury Tablets were safe, with no significant adverse effects on hematological, renal, or liver function parameters. The stable biochemical markers further support the safety of the treatment, indicating no major physiological disruptions. These results suggest that Calcury Tablets are an effective and safe option for the reduction of renal stones and the management of associated symptoms, enhancing the quality of life for patients with stone-related conditions.

Discussion

Modern medicines, including those for treating renal calculi, can offer significant benefits but often come with side-effects like hypokalaemia, dizziness, or gastro-intestinal discomfort. These side-effects can limit their long-term use or require additional interventions, highlighting the need for alternatives with fewer risks. In this context, herbal treatments are emerging as a promising option for kidney stone management.

In recent years, natural active ingredients have demonstrated significant potential in the treatment of kidney stones. Both preclinical and clinical research have provided robust evidence supporting the utilization of these compounds for kidney stones management, as multiple natural active compounds have exhibited efficacy through diverse pathways in both preclinical and clinical investigation.**[8]** A clinical trial investigating Calcury Tablets, an herbal alternative, showed results for managing renal stones. Over three months, patients experienced a significant reduction in both the size and number of stones, with stone size decreasing from 6.5 mm to 4.0 mm and the number of stones reducing from 3.2 to 1.8. Stone passage improved from 55% to 85%, and pain levels were notably reduced, enhancing the overall quality of life. These findings suggest that Calcury Tablets may offer an effective and safer alternative to traditional medications, providing a natural approach to managing kidney stones. Herbs like *Saxifraga ligulata, Boerhaavia diffusa, Saccharum officinarium, tribulus terrestris, picorrhiza kurroa, Crataeva nurvala* have been traditionally used for stone dissolution and prevention, suggesting a natural approach with fewer risks than synthetic medications.

The anti-urolithic activity of *Bergenia ligulata*, particularly through its rhizome's crude aqueous-methanolic extract, has shown promise in inhibiting the formation of CaC2O4 crystals, as well as exhibiting diuretic, hypermagnesiuric, and antioxidant effects. Another study on Bergenia ciliata, when combined with Cystone, demonstrated protective effects on renal function in ethylene glycol-induced kidney stone models, offering improvements in body and organ weight, with fewer areas of glomerular calcification. Historically, *Bergenia ligulata*, known as *Paashanbheda*, has been used in *Ayurvedic* medicine for its lithotriptic and diuretic properties, dating back to ancient texts such as the Charak and Sushruta Samhitas, where it was used to treat uric acid calculi and painful micturition. Urolithiasis (kidney stone disease) affects approximately 12% of the global population, with recurrent stone formation causing significant morbidity and economic burden. Although modern treatments like shock wave lithotripsy and ureteroscopy are available, they come with high costs and considerable side effects. In contrast, several medicinal plants, including Bergenia ligulata, have emerged as effective alternatives,

Providing safer and potentially more accessible solutions to managing kidney stones. These plants may offer a natural remedy with fewer risks, making them a promising avenue for further research and clinical use in treating urolithiasis.**[9]**

Within *Bergenin ligulata*, a range of metabolites including the Cglucoside of 4-O-methyl gallic acid, leucocyanidin, catechin, afzelechin, and paashaanolactone have been identified for their diverse biological activities. Subsequent research has demonstrated the effective reduction of oxidative stress and inflammation by the extract of *Bergenin ligulata* in renal cells under hyperoxaluric conditions. This effect is evidenced by a significant decrease in the expression levels of inflammatory markers such as MAPK, OPN, and NF-κB upon exposure to calcium oxalate challenges. The remarkable suppression of these key bio-markers high lights the potential role of this extract in mitigating inflammatory and oxidative pathways, thereby providing crucial protection against kidney stone formation.**[10]**

Results of a study indicate the presence of anti-urolithic effect of *Boerhaavia diffusa* aqueous extract against CaOx stones in a dose depending manner. It inhibits the CaOx crystal deposition and protects kidney from crystal induced oxidative stress and renal cell injury, possibly mediated through a combination of CaOx crystal inhibitory, hypoxaluric and diuretic activity.**[11]**

The administration of *Tribulus terrestris* (T. terrestris) extract has shown significant alterations in key urinary parameters associated with kidney stone formation in both urolithic patients and healthy individuals. Notably, the extract led to a reduction in serum uric acid levels, which likely contributed to decreased urinary uric acid excretion, helping reduce the risk of urate stone formation. The diuretic effect of the extract increased urine volume, facilitating the dilution of solutes and further lowering stone formation risk. Additionally, T. terrestris influenced calcium and inorganic phosphate metabolism, reducing urinary calcium levels and elevating serum calcium. These effects are similar to those of thiazides, which are used to prevent calcium urolithiasis. Moreover, the magnesium content in the extract likely plays a role in inhibiting calcium oxalate and phosphate crystal formation. The extract also reduced urinary glycosaminoglycan excretion,

Potentially affecting crystal aggregation and preventing stone growth. These findings support the potential of *T. terrestris* as a natural remedy for the prevention and management of kidney stones.**[12]**

Stone formation in the urinary system is a multifaceted process influenced by various factors, including urinary composition, pH levels, and the presence of crystal-forming substances. The herbal drug ***Varuna*** (*Crataeva nurvala*) has shown promise in experimental studies for its anti-lithogenic and anti-crystallization properties. By lowering urinary pH to acidic levels, *Varuna* disrupts conditions favourable for stone formation. Its diuretic properties enhance urinary flow, aiding in the correction of serum and urinary electrolyte imbalances associated with urolithiasis. These combined actions not only help prevent the formation of new stones but also reduce the recurrence of urolithiasis, suggesting Varuna's potential as a supportive therapeutic agent in managing this condition.**[13]**

Conclusion

This clinical trial evaluating Calcury Tablets demonstrated substantial therapeutic benefits in the management of renal stones, highlighting the efficacy and safety of Calcury Tablets. The results showed significant reductions in both the size and number of stones, with a marked increase in stone passage. Pain levels, particularly flank pain and urination discomfort, were notably alleviated, contributing to enhanced patient comfort and overall quality of life. Furthermore, the treatment led to improvements in hydration status and urinary conditions, with a slight increase in urine pH and reductions in urinary calcium and oxalate levels, suggesting better management of stone formation. In terms of safety, Calcury Tablets had no significant adverse effects on key physiological parameters, including renal, hepatic, and haematological functions. Laboratory tests showed stable biochemical markers, reinforcing the safety of the treatment. Participants' quality-of-life scores and satisfaction with treatment also improved significantly, reflecting the positive impact of Calcury Tablets on patient well-being. The clinical evidence from this trial, combined with the promising preclinical findings on the individual herbs involved in the formulation, supports the use of Calcury Tablets as an effective, safe,

And natural alternative for managing renal stones. This treatment offers a promising option for patients seeking a holistic approach compared to conventional medications.

Cost of Study: All medications required during the 3 months of trial were provided by the sponsor. Radio-imaging and biochemical test mentioned were performed at the base line and the end of the trial. The cost for the same was sponsored by the company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest: To avoid any conflict of interest, study was carried out under the unbiased supervision of Dr. Dukle's Vedic Healing Hospital HCP who are not associated with the sponsors.

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