



Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 12:12:36 GMT)

CTRI Number	CTRI/2012/09/002947 [Registered on: 03/09/2012] - Trial Registered Retrospectively	
Last Modified On	10/10/2013	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Drug Ayurveda	
Study Design	Randomized, Parallel Group, Active Controlled Trial	
Public Title of Study	To evaluate the efficacy and the safety profile of Rhubarb and alpha-Keto amino acid supplementation on patients of Chronic kidney disease.	
Scientific Title of Study	Comparative evaluation of efficacy and safety profile of Rhubarb and alpha-Keto analogue of amino acid supplementation on patients of Chronic Kidney Disease.	
Secondary IDs if Any	Secondary ID	Identifier
	15/11/2011	Other
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Department Of Pharmacology And Department Of Medicine, J.N. MEDICAL COLLEGE, A.M.U., ALIGARH, U.P.			
Primary Sponsor	Primary Sponsor Details			
	Name	Department Of Pharmacology And Department Of Medicine		
	Address	Department Of Pharmacology And Department Of Medicine, J.N.MEDICAL COLLEGE, A.M.U., ALIGARH, U.P.		
	Type of Sponsor	Government medical college		
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr IRFAN AHMAD KHAN	Department Of Pharmacology And Department Of Medicine	J.N.MEDICAL COLLEGE, A.M.U., ALIGARH, U.P. Aligarh UTTAR PRADESH	9997448504 irfan1308@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics Committee, J.N. MEDICAL COLLEGE, A.M.U., ALIGARH, U.P.	Approved	16/05/2012	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Chronic kidney disease	
Intervention / Comparator Agent	Type	Name	Details	
	Comparator Agent	conservative management	orally/iv/im for 3 months	
	Intervention	Rhubarb + conservative management	350mg orally BD for 3 months + conservative management for 3 months	
	Intervention	alpha-Keto analogue of amino acid + conservative management	360 mg orally OD for 3 months + conservative management for 3 months	
Inclusion Criteria	Inclusion Criteria			
	Age From	20.00 Year(s)		
	Age To	70.00 Year(s)		
	Gender	Both		
	Details	<ul style="list-style-type: none"> •Chronic kidney disease of different etiology, before ESRD.
 •Patient not on dialysis.
 		
Exclusion Criteria	Exclusion Criteria			
	Details	<ul style="list-style-type: none"> •Pregnancy •Acute infection 		



	<ul style="list-style-type: none"> •Psychotic patient •Critically ill patient •HIV/HBsAg/Anti-HCV and immunocompromised patient. •Severe Renal pathology such as malignancy 				
Method of Generating Random Sequence	Random Number Table				
Method of Concealment	An Open list of random numbers				
Blinding/Masking	Open Label				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>1.Haemogram 2.Urine- Routine & Microscopic 3.Blood Glucose 4.Total Urine Protein(TUP) 5.Blood Urea 6.Serum Creatinine 7.Urine Creatinine</td> <td>Pre-dose and after 1st 2nd 3rd month after starting dosing</td> </tr> </tbody> </table>	Outcome	Timepoints	1.Haemogram 2.Urine- Routine & Microscopic 3.Blood Glucose 4.Total Urine Protein(TUP) 5.Blood Urea 6.Serum Creatinine 7.Urine Creatinine	Pre-dose and after 1st 2nd 3rd month after starting dosing
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Target Sample Size	Total Sample Size=100 Sample Size from India=100 Final Enrollment numbers achieved (Total)= Final Enrollment numbers achieved (India)=				
Phase of Trial	Phase 4				
Date of First Enrollment (India)	01/06/2012				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	Years=0 Months=6 Days=0				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Completed				
Publication Details					
Brief Summary	<p>The study is designed as open-label, randomised, parallel group, study in patients with Chronic Kidney Disease who are not on dialysis. Efficacy and the safety profile of alpha Keto-amino acid and Rhubarb supplementation on patients of Chronic kidney disease is planned to be investigated. Around one hundred subjects will be enrolled into the study in three groups. The subjects will be randomised to receive either conservative management or conservative management + Rhubarb or conservative management + alpha-Keto analogue of essential amino acid. All subjects will be followed up 1,2,3 months to assess efficacy and the safety profile.</p>				