Clinical Trial Details (PDF Generation Date :- Fri, 12 Feb 2021 04:51:51 GMT)

CTRI Number	CTRI/2017/03/008246 [Registered on: 29/03/2017] - **Trial Registered Prospectively**
Last Modified On	16/02/2018
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Low Protein Diet Supplementation Study in Non-Diabetic Kidney Disease Patients
Scientific Title of Study	A Randomized, Open Label, Three Arm, Comparative, Controlled, Single-center Study to Evaluate the Effect of Low Protein Diet Supplementation with Taurine and N-Acetylcysteine (Tab. Nefrosave) and N-Acetylcysteine and Pyridoxamine Dihydrochloride (Tab. Nefrosave Forte) in Preventing Progression of Chronic Renal Failure in Patients with Non-Diabetic Kidney Disease.

Secondary IDs if Any

Secondary ID	Identifier
BVC/CRF-NDKD/2016 Version: 02 Date: 08 September 2016	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Pratim Sengupta
Designation	Consultant Transplant Physician & Nephrologist
Affiliation	Belle Vue Clinic
Address	9, Dr. U.N. Brahmachari Street,Kolkata Kolkata WEST BENGAL 700017 India
Phone	09830099686
Fax	
Email	Pratim.sengupta@gmail.com

Details Contact Person (Scientific Query)

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Name	Dr Pratim Sengupta
Designation	Consultant Transplant Physician & Nephrologist
Affiliation	Belle Vue Clinic
Address	9, Dr. U.N. Brahmachari Street,Kolkata Kolkata WEST BENGAL 700017 India
Phone	09830099686
Fax	
Email	Pratim.sengupta@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Subhash Sugathan
Designation	Consultant Regulatory Affairs and Quality Assurance
Affiliation	QAscent Research Solutions Pvt. Ltd.
Address	B 103, STREET NO. 4, JYOTI COLONY, NEAR DURGAPURI CHOWK, SHAHDRA East DELHI 110032 India

Phone	09971008625
Fax	
Email	subhash@qascentresearch.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> The Kidney Care Society 29/10 Harey Krishno Seth lane, Kolkata-700050, West Bengal, India

Primary Sponsor

Primary Sponsor Details	
Name	Dr Pratim Sengupta
Address	Belle Vue Clinic, 9, Dr. U.N. Brahmachari Street, Kolkata-700017 West Bengal, India
Type of Sponsor	Other [Investigator Initiated]

Details of Secondary Sponsor

Name	Address
QASCENT RESEARCH SOLUTIONS PVT LTD	B 103, Street No. 4, Jyoti Colony, Near Durgapuri Chowk, Shahdara, East Delhi 110032,INDIA

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Pratim Sengupta	Belle Vue Clinic	Nephrology Department, 9, Dr. U.N. Brahmachari Street Kolkata WEST BENGAL	09830099686 Pratim.sengupta@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee Belle Vue Clinic	Approved	20/09/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Non-Diabetic Kidney Disease

Intervention / Comparator Agent

Type	Name	Details
Intervention	Low protein diet supplemented with (Taurine (500 mg) and N-Acetylcysteine (150 mg)) tablet	Low protein diet (0.6g of proteins per kilo of body weight per day) supplemented with Nefrosave (Taurine (500 mg) and N-Acetylcysteine (150 mg)) tablet; Route: Oral; Frequency: One tablet twice daily; Duration of Therapy: 6 Months
Intervention	Low protein diet supplemented with (N-Acetylcysteine (300 mg) and Pyridoxamine Dihydrochloride (50 mg)) tablet	Low protein diet (0.6g of proteins per kilo of body weight per day) supplemented with Nefrosave Forte (N-Acetylcysteine (300 mg) and Pyridoxamine Dihydrochloride (50 mg)) tablet; Route: Oral; Frequency: One tablet twice daily; Duration of Therapy: 6 Months
Comparator Agent	Low protein diet	Low protein diet (0.6g of

			proteins per kilo of body weight per day); Route: Any Route; Frequency: Per day 0.6 g of Protein per kilo of body weight during three meals a day; Duration of Therapy: 6 Months

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	70.00 Year(s)
Gender	Both
Details	1)Ability to understand and provide informed consent for participation in the study 2)Males or females ?18 or ?70 years of age 3)Chronic renal failure patients with GFR more than 15 ml/min/1.73m2 and less than 60ml/min/1.73m2 receiving standard of care based on investigator's discretion 4)Life expectancy greater than one year 5)Non diabetic patients 6)Well controlled blood pressure (MAP10gm/day 6)Hb16g/dl 7)BMI 30 kg/m2 8)Pregnant or nursing females; females of childbearing potential who are unwilling or unable to use an acceptable method of contraception as outlined in this protocol from Day 1 until the month 6 visit 9)Participation in other product clinical trial within 30 days' prior to this trial 10)Any other systemic disease or any other abnormal laboratory values which as per investigator will interfere with patient's participation in study

Method of Generating Random Sequence	Random Number Table
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
The rate of change of GFR (Slope)	Month 3

Secondary Outcome

Outcome	Timepoints
Urinary creatinine clearance	Month 3 and Month 6
Measurement of serum creatinine after 8 hours fast	Month 1, Month 2, Month 3, Month 4, Month 5 and Month 6
eGFR will be calculated by MDRD formula	Month 1, Month 2, Month 3, Month 4, Month 5 and Month 6

Target Sample Size	**Total Sample Size=**75 **Sample Size from India=**75 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	17/04/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**5

	Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	None Yet
Brief Summary	The study protocol BVC/CRF-NDKD/2016 is a randomized, open label, three arm, controlled, single-center study to evaluate the effect of low protein diet supplementation with taurine and n-acetylcysteine (tab. Nefrosave) and n-acetylcysteine and pyridoxamine dihydrochloride (tab. Nefrosave Forte) in preventing progression of chronic renal failure in patients with non-diabetic kidney disease. Patients with chronic renal disease, not on dialysis and satisfying the study eligibility criteria will be enrolled in this study. All patients satisfying the study eligibility criteria will be randomly (using random number table) assigned in 1:1:1 ratio, on any one of the three study arms: **Study Arm-1:** Low protein diet (0.6g/kg BW/day) **Study Arm-2:** Low protein diet (0.6g/kg BW/day) supplemented with Nefrosave tablet (500mg Taurine + 150 mg NAC); **Dose: 1 tab twice daily** **Study Arm-3:** Low protein diet supplemented with Nefrosave Forte tablet (300 mg NAC+ 50 mg pyridoxamine dihydrochloride); **Dose: 1 tab twice daily**