Clinical Trial Details (PDF Generation Date :- Wed, 21 Aug 2013 10:00:03 GMT)

CTRI Number	CTRI/2012/08/002930 [Registered on: 29/08/2012] - **Trial Registered Retrospectively**
Last Modified On	07/08/2012
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Non-randomized, Active Controlled Trial
Public Title of Study	Study of vitamin K2-7 (MK-7) in patients with diabetic peripheral neuropathy and/ or megaloblastic anaemia
Scientific Title of Study	An open labeled study of vitamin K2-7 (MK-7) in patients with diabetic peripheral neuropathy and/ or megaloblastic anaemia

Secondary IDs if Any

Secondary ID	Identifier
VBP–VITAMIN K2-7 (MK-7)/08 (STUDY B) Date:September 2008	Other

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

Details of Principal Investigator	
Name	Dr Vrinda Kulkarni
Designation	Professor & Head of Unit Department of Medicine In-Charge Clinical Haematology
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Yogesh Dound
Designation	Medical Director
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Viridis BioPharma Pvt. Ltd.

Primary Sponsor

Primary Sponsor Details	
Name	Viridis BioPharma Pvt Ltd
Address	6/10, Jogani Industrial Complex, V.N. Purav Marg, Chunabhatti, Mumbai – 400 022, India Tel: +91-22 24055607-09 Fax: +91-22 2405 5952 Email: viridis@vsnl.com
Type of Sponsor	Pharmaceutical industry-Indian

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 Vrinda Kulkarni	B. Y. L. Nair Charitable Hospital	Department of Haematology, Room No. 403, College Bldg. Dr. A. L. Nair Road, Mumbai - 400008 Mumbai MAHARASHTRA	02223027000 02223072663 vrindaklr@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee	Approved	02/07/2010	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Neuropathy occuring because of Megaloblastic Anaemia, Type 2 Diabetes Mellitus

Intervention / Comparator Agent

Type	Name	Details
Intervention	Vitamin K2-7 Capsules	Each capsule of 100 mcg to be given two times in a day orally after food for 8 weeks.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1.Adult male and non-pregnant female patients of the age group 18-60 years 2.Confirmed diagnosis of vitamin B12 deficiency and/or Diabetes Mellitus including pre-diabetics as per WHO criteria 3.Clinical and/or laboratory evidence of peripheral neuropathy 4.No history of drug allergy or significant vitamin K intake 5.Willing to give informed consent

Exclusion Criteria

Exclusion Criteria	
Details	1.Any major systemic illness. 2.Glycosylated hemoglobin more than 9 and Sugar Fasting more than 250 mg%

	3.Patient who are on anti coagulant drug 4.Patient who are on any concomitant medication of neurotoxic or anti-peresthetic drug 5.Patient with sever acute illness 6.Person who are addicted to alcohol

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
The primary objective of the study is to evaluate the activity and tolerability of vitamin MK-7 in patients of diabetes and Megaloblastic anaemia with peripheral neuropathy	Activity and tolerability of vitamin MK-7 in patients of diabetes and Megaloblastic anaemia with peripheral neuropathy after 8 weeks of treatment

Secondary Outcome

Outcome	Timepoints
The secondary objective will be sharply focused on the role of vitamin MK-7 in ameliorating the residual neuropathy symptoms after adequate correction of the underlying inciting event. A record will be maintained of some of the features such as hyper pigmentation, muscle cramps and fatigue for any effect of the intervention	The secondary objective will be sharply focused on the role of vitamin MK-7 in ameliorating the residual neuropathy symptoms after adequate correction of the underlying inciting event. A record will be maintained of some of the features such as hyper pigmentation, muscle cramps and fatigue for any effect of the intervention after 8 weeks of treatment

Target Sample Size	**Total Sample Size=**30 **Sample Size from India=**30
Phase of Trial	Phase 4
Date of First Enrollment (India)	17/02/2010
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**3 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	
Brief Summary	This is an experiential study in ambulatory patients being regularly treated and followed up on OPD basis, the design will be open – labeled , non-randomized but with careful criteria of inclusion and exclusion. Total number of subjects: 30

Evaluation parameters: Efficacy, tolerability & safety of Vitamin K2-7.