Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 02:58:20 GMT)

CTRI Number	CTRI/2017/06/008925 [Registered on: 28/06/2017] - **Trial Registered Retrospectively**
Last Modified On	19/12/2017
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Study of vitamin K2-7 (MK-7) in patients with tingling and numbness due to diabetes and/or vitamin B12 deficiency
Scientific Title of Study	A double blind placebo control Trial to compare the safety and efficacy of Vitamin K2-7 (MK-7) in patients with peripheral neuropathy due to type 2 diabetes mellitus and/ or vitamin B12 deficiency

Secondary IDs if Any

Secondary ID	Identifier
VBP – VITAMIN K2-7 (MK-7)-PN/16 Ver 2 dt 17/02/2017	Protocol Number

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

Details of Principal Investigator	
Name	Dr Milind Devale
Designation	Consulting Physician
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Synergia Life Sciences Pvt Ltd 6/312, Jogani Industrial Complex, V N Purav Marg, Chunabhatti. Mumbai 400 022.

Primary Sponsor

Primary Sponsor Details	
Name	Synergia Life Sciences Pvt Ltd
Address	6/312, Jogani Industrial Complex, V N Purav Marg, Chunabhatti. Mumbai 400 022
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 Milind Devale	Kokan Hospital	Department of Medicine, Areshwar Building, 1st Floor, Mhada Colony, Kokan Nagar, Jogeshwari East, Mumbai 400 060 Mumbai MAHARASHTRA	02228374646 milinddevale75@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Inter System BioMedica Ethics Committee	Approved	25/04/2017	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Neuropathy occurring because of vitamin B12 deficiency and type 2 Diabetes Melitus

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
Comparator Agent	Placebo Capsules	Each capsule identical to Vitamin K2-7 capsule 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	65.00 Year(s)
Gender	Both
Details	1.Male and female aged 18 to 65 who are suffering from type 2 diabetes mellitus and/ or vitamin B12 deficiency. 2.Symptomatic diagnosis of neuropathy (>4 on VAS score). 3.Willing to give informed consent.

Exclusion Criteria

Exclusion Criteria

Details	1.Patients who are suffering from any other systemic illness other than type 2 diabetes mellitus or vitamin B12 deficiency. 2.Patients who are on corticosteroids and oral contraceptives. 3.Patients with seropositive status. 4.Pregnancy. 5.Patients Participation in clinical trials evaluating investigational pharmaceuticals or biologics within 3 months or devices within 30 days of admission to the study. 6.Patients who are on coumarin analogues. 7.Patients who are on Quinine Hydrochloride. 8.History of alcohol. substance abuse or alcoholism, within the previous one year.

Method of Generating Random Sequence	Random Number Table
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Double Blind Double Dummy

Primary Outcome

Outcome	Timepoints
The primary objective of the study is to evaluate the activity and tolerability of Vitamin K2-7 in patients with peripheral neuropathy	Activity and tolerability of vitamin MK-7 in patients of diabetes and Vitamin B12 deficiency with peripheral neuropathy after 12 weeks of treatment.

Secondary Outcome

Outcome	Timepoints
Safety and tolerability; clinical and metabolic variables.	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 12 weeks of treatment

Target Sample Size	**Total Sample Size=**60 **Sample Size from India=**60 **Final Enrollment numbers achieved (Total)=**60 **Final Enrollment numbers achieved (India)=**60
Phase of Trial	Phase 4
Date of First Enrollment (India)	28/04/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	No Publication details
Brief Summary	Recent preliminary open labeled observational study conducted by Vaidya*et al* shows that daily oral dose of 100 mg for 3 months is associated with a reduction in the frequency, intensity, and duration of cramps. In an open labeled study conducted by Kulkarni *et al*, it was shown that vitamin K2-7 at a dose of 100 mcg twice a day for 8 weeks was well tolerated and safe with a therapeutic activity for the symptoms of peripheral neuropathy. Based on the results of these studies, the next study which is a follow up study in larger cohort (N=100) was planned to address the peripheral neuropathy experienced by the patients. Vitamin K2-7 at a dose of 100 mcg twice a day for 8 weeks was well tolerated and safe with a statistically significant reduction in the symptoms of peripheral neuropathy. Based on these results, next study was planed. This study is a double blind placebo controlled Study. N = 60. Evaluation parameters: Efficacy, tolerability and safety of Vitamin K2-7