Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 05:05:59 GMT)

CTRI Number	CTRI/2019/06/019548 [Registered on: 06/06/2019] - **Trial Registered Prospectively**
Last Modified On	25/08/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Other
Public Title of Study	Study of vitamin K2-7(MK-7)levels in patients with tingling and numbness due to diabetes and/or vitamin B12 deficiency
Scientific Title of Study	To measure serum Vitamin K2-7 levels in patients with peripheral neuropathy due to type 2 diabetes mellitus and/ or vitamin B12 deficiency supplemented with Vitamin K2-7

Secondary IDs if Any

Secondary ID	Identifier
SLSPL/MENAQUIN7/032019, version 1, dated 26th Feb 2019	Protocol Number

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

Details of Principal Investigator	
Name	Dr Milind Devale
Designation	Consulting Physician
Affiliation	Kokan Hospital
Address	Department of Medicine, Areshwar Building, 1st Floor, Mhada Colony, Kokan Nagar, Jogeshwari East, Mumbai 400060 Mumbai MAHARASHTRA 400060 India
Phone	
Fax	
Email	milinddevale75@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Yogesh Dound
Designation	Medical Director
Affiliation	Synergia Life Sciences Pvt Ltd
Address	Synergia Life Sciences Pvt. Ltd. Medical Department, 6/312, Jogani Industrial Complex, V. N. Purav Marg, Chunabhatti, Mumbai Mumbai MAHARASHTRA 400 022 India
Phone	0224055607
Fax	
Email	yogesh_dound@yahoo.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Shashank Jadhav
Designation	Medical Associate
Affiliation	Synergia Life Sciences Pvt Ltd
Address	Synergia Life Sciences Pvt. Ltd. Medical Department, 6/312, Jogani Industrial Complex, V. N. Purav Marg, Chunabhatti, Mumbai Mumbai MAHARASHTRA 400022 India

Phone	02224055608
Fax	
Email	shashank@viridisbiopharma.com

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-400022

Primary Sponsor

Primary Sponsor Details	
Name	Synergia Life Sciences Pvt Ltd
Address	Synergia Life Sciences Pvt. Ltd. 6/312, Jogani Industrial Complex, V. N. Purav Marg, Chunabhatti, Mumbai – 400 022, India
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 400060. Mumbai MAHARASHTRA	02228374646 milinddevale75@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Navsanjeevani Hospital Ethics Committee	Approved	18/03/2019	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Type 2 diabetes mellitus without complications
Patients	Vitamin B12 deficiency anemia, unspecified

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	
Method of Concealment	
Blinding/Masking	

Primary Outcome

Outcome	Timepoints
The primary objective of the study is to compare the activity and tolerability of Vitamin K2-7 with placebo in patients with peripheral neuropathy and to measure levels of vitamin K2-7 in serum	0 day, 2nd week, 4th week, 8th week, 12th week

Secondary Outcome

Outcome	Timepoints
Safety and tolerability; clinical and metabolic variables.	0 day, 2nd week, 4th week, 8th week, 12th week

Target Sample Size	**Total Sample Size=**20 **Sample Size from India=**20 **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	Phase 4
Date of First Enrollment (India)	13/06/2019
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**8 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	Sent for publication
Brief Summary	An open labelled trial will be conducted 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. In this trial, 20 patients will be selected as per the inclusion and exclusion criteria after the approval of Ethics Committee and written informed consent is signed. Each patient will either receive vitamin K2-7 capsule or identical placebo. Blood investigations and clinical examination will be done at every visit. The peripheral neuropathy symptoms were checked at 0 day, 2nd week, 4th week, 8th week and 12th week of visit and will be entered in pain score diary. The gradation of peripheral neuropathy was judged by physician based on visual analogue scale. 10 ml blood was withdrawn on 0 day, 4th week and at 8th week and transferred in a cold chain at -65 ± 10°C to Synergia Life Sciences Pvt. Ltd. for analysis of Vitamin K2-7.