



Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 03:50:18 GMT)

CTRI Number	CTRI/2018/05/014246 [Registered on: 30/05/2018] - Trial Registered Prospectively		
Last Modified On	30/04/2021		
Post Graduate Thesis	No		
Type of Trial	Observational		
Type of Study	Prospective Survey		
Study Design	Other		
Public Title of Study	To study the levels of Vitamin K2-7 in patients with diabetes mellitus and hypertension		
Scientific Title of Study	A Prospective Survey of plasma levels of Vitamin K2-7 (MK-7) in population with type 2 diabetes mellitus and hypertension		
Secondary IDs if Any	Secondary ID	Identifier	
	SLSPL/MENAQUIN7/092017	Protocol Number	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
	Name	Dr Dilip Mehta	
	Designation	CEO	
	Affiliation	Synergia Life Sciences Pvt. Ltd.	
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	Phone		
	Fax		
	Email	dilipsmehta39@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.	
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Fax			
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Details Contact Person (Public Query)		Details Contact Person (Public Query)	
	Name	Dr Shashank Jadhav	
	Designation	Medical Associate	
	Affiliation	Synergia Life Sciences Pvt. Ltd.	
	Address	6/312, Jogani Industrial Complex, V. N. Purav Marg, Chunabhatti. Mumbai MAHARASHTRA 400 022 India	
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	Fax		
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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 Dilip Mehta	Kokan Hospital	Areshwar Building, 1st Floor, Mhada Colony, Kokan Nagar, Jogeshwari East, Mumbai 400060 MAHARASHTRA	022-24055608 dilipsmehta39@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Inter System Bio Medica Ethics Committee	Approved	09/10/2017	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Type 2 Diabetes mellitus with Hypertension	
	Patients		Type 2 diabetes mellitus without complications	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	NIL	NIL	
Inclusion Criteria	Inclusion Criteria			
	Age From	28.00 Year(s)		
	Age To	65.00 Year(s)		
	Gender	Both		
	Details	1.Male and female aged 28 to 65 who are confirmed with known diagnosis of type 2 diabetes mellitus with hypertension. 2.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. 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	Not Applicable					
Method of Concealment	Not Applicable					
Blinding/Masking	Not Applicable					
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>The primary objective of the study is to study the levels of Vitamin K2-7 in patients with type 2 diabetes mellitus</td> <td>1 day</td> </tr> </tbody> </table>		Outcome	Timepoints	The primary objective of the study is to study the levels of Vitamin K2-7 in patients with type 2 diabetes mellitus	1 day
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Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>NIL</td> <td>N/A</td> </tr> </tbody> </table>		Outcome	Timepoints	NIL	N/A
Outcome	Timepoints					
NIL	N/A					
Target Sample Size	Total Sample Size=80 Sample Size from India=80 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)	30/05/2018					
Date of First Enrollment (Global)	No Date Specified					
Estimated Duration of Trial	Years=0 Months=0 Days=1					
Recruitment Status of Trial (Global)	Not Applicable					
Recruitment Status of Trial (India)	Closed to Recruitment of Participants					
Publication Details	NA					
Brief Summary	<p>After subjects meet the eligibility criteria an informed consent form (ICF) will be signed before inclusion into the trial. The subjects will undergo besides a detailed history and complete physical examination.</p> <p>For the blood tests 20 cc of blood will be collected in fasting state. A detailed medical history will be taken at the time of screening. Clinical Examination of each subject will be done and recorded in the Case Record Form (CRF).</p>					



The samples will be centrifuged at 3000 rcf for 5 minutes below 10°C to separate plasma. For precaution purpose, the blood samples will be kept in ice cold water bath before centrifugation and during separation. The separated plasma will be transferred to pre-labeled polypropylene tubes and stored upright in a box containing dry ice or in a freezer at a temperature $-65 \pm 10^\circ\text{C}$ for interim storage as required.

Finally the samples will be transferred by keeping them in a box containing dry ice and stored in a bioanalytical freezer at $-65 \pm 10^\circ\text{C}$ until completion of analysis at Synergia Life Sciences Pvt. Ltd.

The concentration of vitamin K2.7 will be measured at Synergia Life Sciences Pvt. Ltd. using single Fluorescence HPLC method, which is validated according to the international guidelines. Literature data of vitamin K2.7 will be used for comparison in view of complete paucity of Indian data on plasma levels of Vitamin K2.7.