



Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 04:14:56 GMT)

CTRI Number	CTRI/2019/03/018278 [Registered on: 26/03/2019] - Trial Registered Prospectively	
Last Modified On	25/08/2020	
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 healthy subjects	
Scientific Title of Study	A prospective survey of plasma levels of vitamin K2-7 (MK-7) in healthy volunteers	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
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
	Address	6/312, Jogani Industrial Complex, V N Purav Marg, Chunabhatti Mumbai MAHARASHTRA 400022 India
	Phone	
	Fax	
	Email	dilipmehta799@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	6/312, Jogani Industrial Complex, V N Purav Marg, Chunabhatti Mumbai MAHARASHTRA 400022 India
	Phone	022-24055607
	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	6/312, Jogani Industrial Complex, V N Purav Marg, Chunabhatti Mumbai MAHARASHTRA 400022 India
	Phone	022-24055608
	Fax	
	Email	shashankviridis@hotmail.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	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 Dilip Mehta	Kokan Hospital	Department of Medicine Areshwar Building, 1st Floor, Mhada Colony, Jogeshwari East, Mumbai 400060 Mumbai MAHARASHTRA	022-24055608 dilipmehta799@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Intersystem BioMedica Ethics Committee	Approved	07/02/2019	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Healthy	
Intervention / Comparator Agent	Type	Name	Details	
Inclusion Criteria	Inclusion Criteria			
	Age From	28.00 Year(s)		
	Age To	45.00 Year(s)		
	Gender	Both		
	Details	Male and female aged 28 to 45 healthy subjects. Having a Body Mass Index (BMI) between 18.5 and 24.9 (both inclusive), calculated as weight in kg / height in sq.m. Willing to give informed consent.		
Exclusion Criteria	Exclusion Criteria			
	Details	People who are suffering from any systemic illness. People who are on corticosteroids and oral contraceptives. People on antibiotics within last week People with seropositive status. Pregnancy and lactating women Participation in clinical trials evaluating investigational pharmaceuticals or biologics within 3 months or devices within 30 days of admission to the study. People who are on coumarin analogues or Quinine Hydrochloride. People who have history of smoking, history of alcohol. substance abuse, within last week.		



Method of Generating Random Sequence		
Method of Concealment		
Blinding/Masking		
Primary Outcome	Outcome	Timepoints
	The primary objective is to study the levels of Vitamin K2-7 in healthy volunteers	1 day
Secondary Outcome	Outcome	Timepoints
	Vitamin K2-7 levels	1 day
Target Sample Size	Total Sample Size=50 Sample Size from India=50 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)	26/03/2019	
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	NIL	
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> <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 temperature -65 ± 10 °C for interim storage as required.</p> <p>Finally the samples will be transferred by keeping them in a box containing dry ice and stored in a bioanalytical freezer at -65 ± 10 °C until completion of analysis at Synergia Life Sciences Pvt. Ltd.</p> <p>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.</p>	