



Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 04:51:00 GMT)

<b>CTRI Number</b>	CTRI/2017/09/009660 [Registered on: 06/09/2017] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	12/09/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	BA/BE	
<b>Type of Study</b>		
<b>Study Design</b>	Single Arm Study	
<b>Public Title of Study</b>	Bioavailability study of Vitamin K2	
<b>Scientific Title of Study</b>	An open label single oral dose bioavailability study of vitamin K2-7 (capsules 1000microgm) of Synergia Lifesciences Pvt.Ltd in Healthy adult, human subjects	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	SLSPL/MENAQUIN7/042016	Protocol Number
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	DrNithya Gogtay
	<b>Designation</b>	Professor (Additional)
	<b>Affiliation</b>	Seth GSMC and KEM hospital
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Synergia Lifesciences Pvt.Ltd.Jogani Industrial Complex,Mumbai 400 022			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	Synergia Lifesciences PvtLtd			
<b>Address</b>	6/312,Jogani Industrial Complex,V.N Purav Marg,Chunabhatti,Mumbai 400 022			
<b>Type of Sponsor</b>	Pharmaceutical industry-Indian			
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	Dr Nithya Gogtay	Seth GSMC and KEM Hospital	Phase I unit, Department of Clinical Pharmacology, Seth GSMC and KEM Hospital, Parel, Mumbai Mumbai MAHARASHTRA	02224133767 njgogtay@hotmail.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Institutional Ethics Committee-1,Seth GSMC and KEM hospital	Approved	13/06/2017	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Healthy Human Volunteers		Healthy volunteers will be enrolled	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Vitamin K 2-7 (1000 microgram)	Naturally occurring Vitamin K analogue	
	Comparator Agent	Nil	Nil	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	18.00 Year(s)		
	<b>Age To</b>	45.00 Year(s)		



	<b>Gender</b>	Both
	<b>Details</b>	Healthy Volunteers
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	Hypersensitivity to vitamin K and consumption of fermented food in last 24 hours
<b>Method of Generating Random Sequence</b>	Not Applicable	
<b>Method of Concealment</b>	Not Applicable	
<b>Blinding/Masking</b>	Not Applicable	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Evaluation of Bioavailability and pharmacokinetic profile of test drug	After study completion
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Safety of the test drug	Throughout the study
<b>Target Sample Size</b>	<b>Total Sample Size=16</b> <b>Sample Size from India=16</b> <b>Final Enrollment numbers achieved (Total)=0</b> <b>Final Enrollment numbers achieved (India)=16</b>	
<b>Phase of Trial</b>	Phase 4	
<b>Date of First Enrollment (India)</b>	22/09/2017	
<b>Date of First Enrollment (Global)</b>	16/09/2017	
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=6</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Completed	
<b>Publication Details</b>	The manuscript is being written up for publication	
<b>Brief Summary</b>	<p>Safety</p> <p>Data from all participants receiving one dose of Vitamin K2-7 capsules were included in safety data. No adverse events/serious adverse events were noted. The formulation Vitamin K2-7 Capsules of 1000 µg was well tolerated by the participants.</p> <p>Pharmacokinetics</p> <p>The pharmacokinetic profile of 1000 µg of Vitamin K2-7 Capsules in healthy, adult, human male participants under fed condition are as follows:</p>	



$C_{max}$  -  $34.6 \pm 13.5$   $\mu$ g/ml,  $t_{max}$  -  $5 \pm 1.8$  hours, AUC (0-t) -  $263.5 \pm 73.2$  mg/ml.hr and AUC (0- $\infty$ ) -  $1014 \pm 1466$  mg.hr/L