Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 04:15:56 GMT)

CTRI Number	CTRI/2019/12/022361 [Registered on: 13/12/2019] - **Trial Registered Prospectively**
Last Modified On	30/04/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Single Arm Study
Public Title of Study	Multiple oral dose pharmacokinetics of vitamin K2-7 capsules 350 mcg under fed condition
Scientific Title of Study	An open label, parallel study to evaluate the steady state pharmacokinetics of Vitamin K2-7 capsules 350 mcg of Synergia Life Sciences Pvt. Ltd after multiple dose administered in normal, healthy, adult, human male subjects under fed condition

Secondary IDs if Any

Secondary ID	Identifier
0381-19 Version: 1.0 dated 24 Oct 2019	Protocol Number

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

Details of Principal Investigator	
Name	Dr Alpesh Parmar
Designation	Principal Investigator
Affiliation	Lambda Therapeutic Research Ltd.
Address	Clinical Department. Lambda house, Plot No. 38, Survey no. 388,Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad Ahmadabad GUJARAT 382481 India
Phone	91-79-40202020
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Details Contact Person (Scientific Query)

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Name	Dr Alpesh Parmar
Designation	Principal Investigator
Affiliation	Lambda Therapeutic Research Ltd.
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Shashank Jadhav
Designation	Medical Director
Affiliation	Synergia Life Sciences Pvt Ltd
Address	1503, Universal Majestic, P L Lokhande Marg, Ghatkopar Mankhurd Link Road, Govandi. Mumbai MAHARASHTRA 400043 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

Primary Sponsor

Primary Sponsor Details	
Name	Synergia Life Sciences Pvt Ltd
Address	1503, Universal Majestic, P L Lokhande Marg, Ghatkopar Mankhurd Link Road, Govandi. Mumbai 400 043.
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NA	NA

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Alpesh Parmar	Lambda Therapeutic Research Ltd	Lambda house, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India. Ahmadabad GUJARAT	91-79-40202020 91-79-40202021 alpeshjparmar@lambda-cro.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Conscience Independent Ethics Committee	Approved	01/11/2019	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
Intervention	Vitamin K2-7	Vitamin K2-7 capsule of 350 mcg to be consumed once daily immediately after dinner for 21 days.
Comparator Agent	NA	NA

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	45.00 Year(s)
Gender	Male
Details	1. Non-smokers, normal, healthy, adult, human male volunteers between 18 to 45 years of age (both inclusive). 2. Having a Body Mass Index (BMI) between 18.5 to 30.0 (both inclusive), calculated as weight in kg / height in sq.m. 3. Not having any significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, laboratory evaluations, 12-lead ECG and X-ray chest (P/A view)

	recordings. 4. Able to understand and comply with the study procedures, in the opinion of the investigator. 5. Able to give voluntary written informed consent for participation in the study.

Exclusion Criteria

Exclusion Criteria	
Details	1. Known hypersensitivity to Vitamin K2-7 or any excipients or any related drug or any substance. 2.History or presence of any disease or condition which might compromise the haemopoietic, renal, hepatic, endocrine, pulmonary, central nervous, cardiovascular, immunological, dermatological, gastrointestinal or any other body system. 3. Ingestion of a medication (prescribed & over the counter (OTC) medication including herbal remedies) at any time within 14 days prior to first dosing. In any such case subject selection will be at the discretion of the Principal Investigator / designee. 4. Any history or presence of asthma (including aspirin induced asthma) or nasal polyp or NSAIDs induced urticaria. 5. A recent history of harmful use of alcohol (less than 2 years) i.e., alcohol consumption of more than 14 standard drinks per week for men (A standard drink is defined as 360 ml of beer or 150 ml of wine or 45 ml of 40% distilled spirits, such as rum, whisky, brandy etc), or consumption of alcohol or alcoholic product within 48 hours prior to check-in. 6. Smokers or who have smoked within last 06 months prior to start of the study. 7. Consumption of natto or any fermented food products such as Dosa, Ideli, Curd, Yogurt and other vitamin K containing products within 72 hours prior to check in. 8. The presence of clinically significant abnormal laboratory values during screening.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To characterize the Steady state pharmacokinetic profile of Vitamin K2-7 capsule 350 mcg after multiple oral dose administration in normal, healthy, adult, human male subjects under fed condition.	21 days

Secondary Outcome

Outcome	Timepoints
To monitor the safety of the subjects	22 days

Target Sample Size	**Total Sample Size=**15 **Sample Size from India=**15 **Final Enrollment numbers achieved (Total)=**14 **Final Enrollment numbers achieved (India)=**14
Phase of Trial	Phase 2
Date of First Enrollment (India)	19/12/2019

Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	An open label, parallel study to evaluate the steady state pharmacokinetics study in normal, healthy, adult, human male subjects under fed condition. No. of subjects: 15 Vitamin K2-7 capsule of 350 mcg to be consumed everyday immediately after dinner for 21 days. Vitamin K2-7 along with Uncarboxylated Osteocalcin (ucOC) and Carboxylated Osteocalcin (cOC) will be measured at baseline, 3rd, 7th, 14th and 21st day.