Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 15:45:23 GMT)

CTRI Number	CTRI/2013/06/003770 [Registered on: 19/06/2013] - **Trial Registered Retrospectively**
Last Modified On	01/09/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Randomized, Crossover Trial
Public Title of Study	Clinical Study For Studying the Absorption of Vitamin D3 Oral Spray in comparison with Vitamin D3 Capsule In Healthy and Unhealthy Subjects Under Fed Conditions After One Month Dose Administrations.
Scientific Title of Study	A Randomized, Open-label, Balanced, Two-period, Two-treatment, Two way Cross-over Study For Studying the Absorption of Test Product: D-LIGHT™ (Vitamin D3 Oral Spray) in comparison with Reference Product: Uprise-D3 (Vitamin D3 Capsule 1000 IU) In Healthy and Unhealthy Subjects Under Fed Conditions After One Month Dose Administrations.

Secondary IDs if Any

Secondary ID	Identifier
ECTS/13/003, Version No 01 Dated 13 APR 2013	Protocol Number

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

Details of Principal Investigator	
Name	Dr Milan Satia
Designation	Chief Executive Officer
Affiliation	Ethicare Clinical Trial Services
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Pharma Base S.A.

Primary Sponsor

Primary Sponsor Details	
Name	Pharma Base SA
Address	Pharma Base S.A. Schwerzistrasse 6, CH-8807 Freienbach, Switzerland
Type of Sponsor	Pharmaceutical industry-Global

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 Akhil Mukim	ALL WELL	Mukim Medical Nursing Home & Heart Clinic, Room No 235, 2nd floor, Platinum Plaza, Judges Bunglow Road, Vastrapur, Ahmedabad – 380015, Gujarat, India Ahmadabad GUJARAT	9825074444 drmukim@indiatimes.com
Dr K D Tibrewala	Dr K D Tibrewala Clinic	A-61, 62; 6th Floor, Pariseema, Opp. Lal Bungalow, C.G. Road, Ahmedabad – 380006 Ahmadabad GUJARAT	07922866311 kdtibrewala@hotmail.com
Dr Mahendra Bhavsar	Dr Mahendra Bhavsar Clinic	Room No 11, 2nd Floor, Vishvamitra Complex, Nr. Sardar Patel Colony, Stadium Road,Ahmedabad – 380014 Ahmadabad GUJARAT	09824043226 drmsbhavsar@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Spandan Independent Ethics Committee , Ahmedabad for Dr K D Tibrewala	Approved	13/05/2013	Yes
Spandan Independent Ethics Committee, Ahmedabad for Dr Akhil Mukim	Approved	13/05/2013	Yes
Spandan Independent	Approved	13/05/2013	Yes

Ethics Committee, Ahmeddabad for Dr Mahedra Bhavasar			

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Malabsorption disease: (Ulcerative Colitis and Steatorrhoea) in Healthy and Unhealthy subjects.

Intervention / Comparator Agent

Type	Name	Details
Intervention	D-LIGHT™	Vitamin D3 Oral Spray, Dose: 1000 IU, Frequency: 2 spray/day (500IU/spray), Route of administration: Oral, Total Duration: 1 month
Comparator Agent	Uprise-D3	Vitamin D3 Capsule, Dose: 1000 IU, Frequency: 1 Capsule/day, Route of Administration: Oral, Total Duration: 1 month

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1.Written informed consent for participation in the study by the subject. 2.Subjects of either sex, between 18 and 65 years of age (both inclusive). 3.Having a Body Mass Index (BMI) between 18.0 and 30.0 (kg/m2). 4.Able to comply with study procedures in the opinion of the investigator. 5.For healthy subjects: 5.1Not having any significant diseases or clinically significant abnormal findings during medical history, physical examination, laboratory evaluations etc. 5.2Subject having no any history of significant smoking habit (more than 10 cigarettes or beedi (Indian cigarette)'s/day). 6.For unhealthy subjects: 6.1Subjects with confirmed diagnosis of any one of the following Malabsorption disease condition: •Ulcerative Colitis •Steatorrhoea

Exclusion Criteria

Exclusion Criteria	
Details	1.Subjects who are already taking a vitamin D supplement regularly (once per week or more), or travelling to sunny areas or using a tanning bed during the previous 3 months. 2.Subjects with history of uncontrolled hypertension. 3.Seated blood pressure less than 110/70 mmHg or pulse rate less than 60 or more than 100 beats per minute at screening. 4.Subjects with history of hypercalcemia, hyperparathyroidism or osteomalacia. 5.History or presence of cancer. 6.Difficulty in swallowing solids like tablets or capsules. 7.Subjects with history of peptic ulcer disease, frequent dyspepsia or bleeding. 8.Subjects with moderate or severe cognitive impairment.

	9.No history of any medical condition or addictive disorder or laboratory abnormality that may increase the risks associated with disease condition in unhealthy subjects. 10.Positive screening test for any one or more: HIV I & II and Hepatitis B. 11.Any food allergy, intolerance, restriction or special diet that, in the opinion of the investigator could contraindicate the subject's participation in this study. 12.Subjects with any condition which in the opinion of the investigator makes the subject unsuitable for inclusion. 13.Female subject who is pregnant or willing to get pregnant, not ready to use contraceptive measures during the trial period or breast feeding.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Absorption of test and reference product in healthy and unhealthy subjects.	90 Days

Secondary Outcome

Outcome	Timepoints
Safety, Tolerability and Compliance of test and reference product	90 Days

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40 **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 3
Date of First Enrollment (India)	23/05/2013
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)	Open to Recruitment
Publication Details	
Brief Summary	To evaluate absorption of test and reference product in healthy and unhealthy subjects of **Test Product:** D-LIGHT™ (Vitamin D3 Oral Spray) in comparison with **Reference Product:** Uprise-D$_3$ (Vitamin D3 Capsule 1000 IU) In Healthy and Unhealthy Subjects Under Fed Conditions After One Month Dose Administrations. Eligible patients with balanced male-female will be randomised in 1:1 ratio of test and reference product to receive the study treatment of Vitamin D3 Oral spray 500IU two times or Vitamin D3 Capsule 1000IU half an hour after heavy meal in healthy and unhealthy subject for 1 month. After the washout period of one month, subjects will receive treatment in cross over fashion and treatment will be changed from test to reference and vice versa. Vitamin D3 level is measured in healthy and unhealthy subjects on the day of 1st dose and at the end of study period - I,same procedure will be apply for period-II. Safety will also be evaluated based on measurements of hematology (CBC), biochemical parameters (serum creatinine, total bilirubin, urea, SGPT, SGOT, alkaline phosphatase, calcium) and urinalysis.