Clinical Trial Details (PDF Generation Date :- Tue, 19 Oct 2021 13:33:31 GMT)

CTRI Number	CTRI/2013/05/003663 [Registered on: 22/05/2013] - **Trial Registered Prospectively**
Last Modified On	18/11/2014
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Nutraceutical
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	A clinical study to Assess the Efficacy and Tolerability of UC-II® in modulating knee joint function
Scientific Title of Study	A Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Efficacy and Tolerability of UC-II® in modulating knee joint function

Secondary IDs if Any

Secondary ID	Identifier
LPPL/IH/OA/001/11, Version no.2.0 Dated: 26th Apr 2012	Protocol Number

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

Details of Principal Investigator	
Name	Mr Sanjib Kumar Panda
Designation	Overall Trial Coordinator
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Mr Sanjib Kumar Panda
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Source of Monetary or Material Support

Source of Monetary or Material Support
> InterHealth Nutraceuticals 5451 Industrial Way Benicia, California 94510

Primary Sponsor

Primary Sponsor Details	
Name	InterHealth Nutraceuticals
Address	5451 Industrial Way Benicia, California 94510
Type of Sponsor	Other [Nutraceutical Company]

Details of Secondary Sponsor

Name	Address
Laila Pharmaceuticals Pvt Ltd	No 7, Arudra Street, TS Krishna Nagar, Mogappair, Chennai 600 037

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Siva G Prasad	Apollo Hospitals	Door.No-10-50-80 Waltair Main Road, Ramnagar Visakhapatnam-530002 Andhra Pradesh. Visakhapatnam ANDHRA PRADESH	9441606666 08912560858 dr_sivaji@yahoo.co.in
Dr K Rajapandian	Apollo speciality Hospitals	Lake View Road, K.K.Nagar,Madurai-625020 Madurai TAMIL NADU	9965528552 0452-2581157 madurai@aherf-smo.org
Dr K Balakondiah	Bollineni Superspeciality Hospital	Dargamitta,Nellore Nellore ANDHRA PRADESH	08612312777 bakolaxmi@rediffmail.com
Dr Balaji Thiruvadi	Gram Clinical Research Karpagam Hospital	100 Vakkil New Street,Simmakkal, Madurai-625001 Madurai TAMIL NADU	0452-4243614 0452-4353614 drbalaji@gramclin.com
Dr Saji PO Thomas	Little Flower Hospital & Research Centre	Post Box 23,Angamaly-683572 Ernakulam KERALA	04843096666 spotsmsa4@hotmail.com
Dr Karlapudi Vasu	Pujitha Hospital	NTR Circle, Pantakaluva Road, Patamata, Vijayawada Krishna-520010 Krishna ANDHRA PRADESH	9848112727 0866-2495722 drkarlapudi@rediffmail.com
Dr Sundar Subramanian	V S Hospital	13 East Spurtank road, Chetpet, Chennai-600031 Chennai TAMIL NADU	04442001000 drsundar69@hotmail.com
Dr MAVV Prasad	Vijaya Superspeciality Hospitals	Raghava cine complex road, Pugathota, SPSR Nellore-Andhra	09885226009 0861-2300068 mavvprasad@gmail.co

		Pradesh-524001 Nellore ANDHRA PRADESH	m
Dr Meenakshi Sundaram	Vinayaka Mission Hospital	NH-47,Sankari Main Road, Veerapandi Post, Salem - 636 308,Tamil Nadu Salem TAMIL NADU	04273982000 meenakshiortho@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Apollo hospitals vizag Ethics Committee for Dr.Siva G Prasad	Approved	30/01/2014	No
Bezawada central Ethics committee for Dr.K.Vasu	Approved	03/10/2013	Yes
Ethics Committee for Dr.K. Rajapandian	Approved	07/10/2013	No
GRAM Ethics Committee for Dr.Balaji Thiruvadi	Approved	28/05/2012	No
Independent Ethics Committee- Aditya for Dr.Sundar Subramanian	Approved	18/06/2012	Yes
Little Flower Hospital Independent Ethics Committee for Dr.Saji Thomas	Approved	11/02/2013	Yes
Simhapuri Independent Ethics Committee for Dr.Balakondaiah	Approved	21/11/2012	Yes
Vijaya Ethics Committee for Dr.M.A.V.V.Prasad	Approved	28/11/2013	No
Vinayaka Mission Hospital Institutional Ethics Committee for Dr.Meenakshi Sundaram	Approved	28/05/2012	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Osteoarthritis of the knee

Intervention / Comparator Agent

Type	Name	Details
Intervention	UC-II® (Undenatured Type II Collagen)	2 capsules to be taken every morning with breakfast and every evening before bedtime for 180 days
Comparator Agent	Glucosamine + Chondroitin	2 capsules to be taken every morning with breakfast and every evening before bedtime for 180 days
Comparator Agent	Placebo	2 capsules to be taken every

		morning with breakfast and every evening before bedtime for 180 days

Inclusion Criteria

Inclusion Criteria	
Age From	40.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	1.Ambulatory, male and female subjects 40 – 75 years of age with a Body Mass Index (BMI) of approximately 18 to 30 kg/m2 2.Females of childbearing potential must agree to use a medically approved form of birth control and have a negative urine pregnancy test result throughout the study. Female subjects of non childbearing potential must be amenorrheic for at least 1 years or had a hysterectomy and/or bilateral oophorectomy 3.Unilateral or bilateral OA of the knee for greater than 3 months (ACR criteria) and Kellgren and Lawrence radiographic grading of 1 or 2 4.VAS score during the most painful knee movement between 40-70 mm after 7 days withdrawal of excluded medications 5.Lequesne's functional index score between 6-10 points after 7 days withdrawal of excluded medications 6.Results of screening and clinical laboratory tests are within normal range or considered not clinically significant by the Principal Investigator 7.Be willing and able to participate in all scheduled visits, study plan, tests and other trial procedures according to the clinical protocol 8.Be willing to refrain from taking ibuprofen, aspirin or other NSAIDS (other than acetaminophen/paracetamol as rescue medication) or any other pain reliever (OTC or prescription) during the entire trial. 9.Provide a personally signed and dated informed consent indicating that the subject has been informed of all pertinent aspects of the trial.

Exclusion Criteria

Exclusion Criteria	
Details	1.History of hypersensitivity to NSAIDS, or any other similar pharmacological agents or components of the products 2.History of hypersensitivity to eggs, chicken or fowl, or shellfish 3.History of underlying inflammatory arthropathy or severe RA or OA (VAS score greater than 70) 4.Hyperuricemia (>440 µmol/L) and/or past history of gout 5.Expectation of surgery in the next 4 months 6.Recent injury in the area affected by OA of the knee (past 4 months) 7.Have taken any corticosteroid, indomethacin, glucosamine + chondroitin, within 3 months prior to the Randomization visit, Day 1 (Visit 2) or intra-articular treatment / injections with corticosteroid or hyaluronic acid within 6 months preceding the randomization visit. 8.History of congestive heart failure 9.Anticipated problems with product consumption 10.Evidence or history of clinically significant (in the judgment of the Investigator) hematological, renal, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, neurologic diseases, or malignancies within the last 5 years 11.History of Systemic Lupus Erythematosus (SLE) 12.High alcohol intake (>2 standard drinks per day) or use of recreational drugs (such as cocaine, methamphetamine, marijuana, etc) 13.Females who are pregnant or lactating or planning to become pregnant 14.History of psychiatric disorder that may impair the ability of subjects to provide written informed consent 15.Have taken acetaminophen/paracetamol, ibuprofen, aspirin or other NSAIDS or any other pain reliever (OTC or prescription) or any

	natural health product, (excluding vitamins), within 7 days prior to the Screening Visit (Visit 1) 16.Participation in any other trials involving investigational or marketed products within 30 days prior to the Screening Visit (Visit 1)

Method of Generating Random Sequence	Permuted block randomization, fixed
Method of Concealment	An Open list of random numbers
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
The primary endpoint is the change in the overall WOMAC score from baseline	Day1,Day7,Day30,Day60,Day90,Day120,Day150 and Day180

Secondary Outcome

Outcome	Timepoints
Change from baseline in VAS score	Day1,Day7,Day30,Day60,Day90,Day120,Day150 and Day180
Change from baseline in LFI score	Day1,Day7,Day30,Day60,Day90,Day120,Day150 and Day180
Change from baseline in Serum biomarker, COMP	Day1,Day90 and Day180
Mean change in WOMAC subscale (pain, stiffness and physical function) assessment time points	Day7,Day30,Day60,Day90,Day120,Day150 and Day180
Change from baseline in Knee flexion range of motion	Day1,Day7,Day30,Day60,Day90,Day120,Day150 and Day180

Target Sample Size	**Total Sample Size=**96 **Sample Size from India=**96 **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	Phase 3
Date of First Enrollment (India)	01/06/2013
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	

UC II® (Undenatured (native) type-II collagen) is a dietary supplement obtained from chicken sternum cartilage. Extensive preclinical and clinical studies in large population demonstrates the benefits of UC-II® for increasing joint comfort, mobility and flexibility. UC-II® is found to be both effective and safe for long-term usage without adverse events or gross perturbation to liver, kidney or heart biomarkers. Overall, supplementation

with UC-II® improves quality of life by alleviating joint pain thereby enhancing daily activities in osteoarthritic sufferers.

The proposed clinical trial is a Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Efficacy and Tolerability of UC-II® in modulating knee joint function. In this study a total of 66 subjects with age between 40-75 years will be recruited and randomized in three different groups (UC-II, Glucosamine + Chondroitin or Placebo).The dosing period is for 180 days per subject with the follow up visits from day 1, 7, 30, 60, 90, 120,150 and 180.The intensity of pain and quality of life will be assessed by using WOMAC, LFI and VAS. Also apart from normal laboratory parameters, the serum biomarkers like COMP and CRP will be analyzing during day 1, day 90 and day 180.