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A double-blind, active-controlled, randomized, parallel group multicentric study to investigate the safety, tolerability and efficacy of reparagen - a dietary supplement compared to glucosamine sulphate in patients with moderate osteoarthritis of the knee

ISRCTN	ISRCTN25438351
ClinicalTrials.gov identifier	
Public title	A double-blind, active-controlled, randomized, parallel group multicentric study to investigate the safety, tolerability and efficacy of reparagen - a dietary supplement compared to glucosamine sulphate in patients with moderate osteoarthritis of the knee
Scientific title	
Acronym	REPVGLUOA
Serial number at source	VL/050421/SP
Study hypothesis	That reparagen is safe and effective in patients with moderate osteoarthritis, and compared to glucosamine sulphate, reparagen has a faster onset of action with an overall greater response.
Ethics approval	Approved by the Institutional Ethics Committee of KJ Somaiya Medical College and Hospital, Mumbai, India, submitted on 30/12/2005, approved on 08/02/2006
Study design	Double-blind, active-controlled, randomized, parallel group multicentric study
Countries of recruitment	India
Disease/condition/study domain	Moderate osteoarthritis of the knee
Participants - inclusion criteria	1. Ambulatory adult patients of either sex >20 years of age 2. Patients with moderate osteoarthritis of the knee, clinically detected and/or diagnosed as per radiological examination and American Rhematology Association (ARA) functional classification 3. ARA functional class II or III 4. Kellgren Lawrence for knee osteoarthritis grade II, grade III 5. Patient's assessment of overall pain score between 40 and 100 mm on a pain-visual analogue scale after washout period
Participants - exclusion criteria	1. Arthritis other than osteoarthritis 2. Arthroscopy of either knee in the past year 3. Administration of intraarticular steroids within the past three months or hyaluronic acid in the last nine months 4. Known adverse responses to non-steroidal anti-inflammatory drugs (NSAIDs), suspected hypersensitivity, allergy or other contraindication to any compounds present in the study medication 5. Significant gastrointestinal (GI) diseases or previous GI upset to NSAID administration 6. Pregnant or lactating women or woman of child-bearing age not following adequate contraception 7. Evidence of severe renal, hematopoetic disease or severe cardiac insufficiency as revealed by laboratory investigations and other tests 8. Moderate to severe peripheral neuropathy or other neurological disorders 9. Unwilling or unable to come to regular follow-up studies 10. Any condition which in the opinion of the investigator does not justify patient inclusion in the

	study 11. Inability to give informed consent
Anticipated start date	13/05/2006
Anticipated end date	30/09/2006
Status of trial	Completed
Patient information material	
Target number of participants	80
Interventions	Reparagen, a combination of a cat's claw extract (Uncaria guianensis), a herbal medicine from the Amazon, and RNI 249, an extract of maca (Lepidium meyenii) a vegetable native to the Andes compared to glucosamine sulphate
Primary outcome measure(s)	1. Pain visual analogue score 2. Modified Western Ontario and McMaster University osteoarthritis index (WOMAC)
Secondary outcome measure(s)	1. Serum insulin-like growth factor-1 (IGF-1) 2. Global assessment of therapy 3. Patient's opinion 4. Consumption of rescue medication
Sources of funding	Santerra Pharmaceuticals LLC (USA) - contracted by Rainforest Nutritionals, Inc.
Trial website	http://www.santerra-pharma.com
Publications	Results in http://www.ncbi.nlm.nih.gov/pubmed/17974032
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