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

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### 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](http://www.santerra-pharma.com)

### Publications


### Contact name

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### Sponsor

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### Sponsor website

[http://www.santerra-pharma.com](http://www.santerra-pharma.com)
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