

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

Submission date 18/05/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/03/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

VL/050421/SP

Study information

Scientific Title

Acronym

REPVGLUOA

Study objectives

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 required

Old ethics approval format

Ethics approval(s)

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

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Moderate osteoarthritis of the knee

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

ReparaGen, glucosamine sulphate

Primary outcome(s)

1. Pain visual analogue score
2. Modified Western Ontario and McMaster University osteoarthritis index (WOMAC)

Key secondary outcome(s)

1. Serum insulin-like growth factor-1 (IGF-1)
2. Global assessment of therapy
3. Patient's opinion
4. Consumption of rescue medication

Completion date

30/09/2006

Eligibility

Key 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 Rheumatology 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key 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, hematopoietic 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

Date of first enrolment

13/05/2006

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

India

Study participating centre

Vedic Lifesciences

Mumbai

India

400 053

Sponsor information

Organisation

Santerra Pharmaceuticals LLC (USA)

Funder(s)

Funder type

Industry

Funder Name

Santerra Pharmaceuticals LLC (USA) - contracted by Rainforest Nutritionals, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	31/10/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes