

# 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

<b>Submission date</b> 18/05/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/03/2008	<b>Condition category</b> 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

## Study website

<http://www.santerra-pharma.com>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

13/05/2006

## **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

## **Age group**

Adult

## **Sex**

Both

**Target number of participants**

80

**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)

**Sponsor details**

Santerra Pharmaceuticals LLC  
12721 Strickland Road  
Raleigh  
United States of America  
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+1 919 847 2221  
pbobrowski@santerra-pharma.com

**Sponsor type**

Industry

**Website**

<http://www.santerra-pharma.com>

## Funder(s)

**Funder type**

Industry

**Funder Name**

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

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**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?
<a href="#">Results article</a>	Results	31/10/2007		Yes	No