ISRCTN25438351 https://doi.org/10.1186/ISRCTN25438351

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

Registration date
22/06/2006

Last Edited
18/03/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
Mr Jayesh Chaudhary

Contact details
Vedic Lifesciences
118 Morya House
Off Link Road
Andheri (West)
Mumbai
India
400 053
+91 (0)22 5693 9757
jayesh@ayuherbal.com

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 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

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, 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

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
27613
+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?
Results article	Results	31/10/2007		Yes	No