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A double blind randomised placebo controlled trial to compare two doses of a mineral supplement and a herbomineral combination in alleviating the symptoms of osteoarthritis of the knee

Submission date
21/02/2005

Recruitment status
No longer recruiting

Registration date
07/03/2005

Overall study status
Completed

Last Edited
18/02/2008

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

Contact information

Type(s)
Scientific

Contact name
Mr Jayesh Chaudhary

Contact details
118, Morya House
Off Link Road
Anheri-west
Mumbai
India
4000 053
+91 (0)22 267 33092
vedic@ayuherbal.com

Additional identifiers

Protocol serial number
3062/RF

Study information

Scientific Title

Acronym
HerbomineralOA

Study objectives
It was proposed that a natural mineral supplement, which has been shown to attenuate the degradation of human cartilage caused by the cytokine, interleukin-1 (IL-1), and catabolic pathways like nitric oxide production, would provide relief of the symptoms of osteoarthritis (OA) of the knee. The study examined two doses of this mineral supplement, as well as the combination of the low dose with a botanical extract, cat's claw, which had previously been reported to be effective in treating OA. These three groups were compared to a placebo treated group and treatment was for an 8 week period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Ethics Committee of K.J. Somaiya Medical College & Hospital, Mumbai (India) and was in compliance with the Helsinki Declaration.

Study design
Randomised, double-blind, placebo-controlled multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis (OA) of the knee

Interventions
Group A: Mineral supplement SierraSil (high dose 750 mg/capsule, 4 capsules a day)
Group B: Mineral supplement SierraSil (low dose 500 mg/capsule, 4 capsules a day)
Group C: Herbomineral supplement (low dose SierraSil 500 mg, 4 times a day, plus cat's claw extract, vincaria, 25 mg/capsule, 4 times a day)
Group D: Placebo (750 mg/capsule, 4 times a day)
Rescue Medication: Paracetamol

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mineral supplement (SierraSil), herbomineral supplement (SierraSil, cat's claw extract and vincaria)

Primary outcome(s)
Western Ontario McMaster Arthritis Index (WOMAC) A, B, C and total scores (scores are for pain, stiffness, function).

Key secondary outcome(s))
1. Visual Analogue Score (VAS) for pain
2. Consumption of rescue medication (paracetamol)
3. Recovery (physician and patients' assessments)
4. Tolerability
5. Safety variables
6. Vitals (pulse rate, temperature, blood pressure, respiration rate) measured at baseline and weeks 1, 2, 4, 6 and 8
7. Laboratory investigations - complete blood count, serum glutamate pyruvate transaminase (SGPT), serum creatinine, erythrocyte sedimentation rate (ESR) at screening and week 8, adverse event monitoring at week 1, 2 4, 6, 8.

Completion date
01/01/2005

Eligibility

Key inclusion criteria
1. Ambulatory adults of either sex of greater than 20 years of age
2. OA of the knee diagnosed as per radiologic examination and the American Rheumatology Association (ARA) functional classification (II or III) or Kellgren-Lawrence Classification of grade II or grade III
3. Functional assessments of overall pain of at least 50 mm on a 100 mm Visual Analogue Scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Osteoarthritis of grade I or grade IV
2. ARA functional class I or IV
3. Any arthritis other than OA
4. Arthroscopy of either knee for the past year
5. Intraarticular steroids for the last 3 months or hyaluronic acid in the last 9 months

6. Pregnant or lactating women
7. Evidence of severe renal, haematologic disease or severe cardiac insufficiency as revealed by laboratory investigations and other tests
8. Unwilling to come to regular follow up visits for the duration of the study
9. Moderate to severe peripheral neuropathy
10. Any condition that the investigator feels does not allow participation in the study

Date of first enrolment
01/09/2004

Date of final enrolment
01/01/2005

Locations

Countries of recruitment
India

Study participating centre
118, Morya House
Mumbai
India
4000 053

Sponsor information

Organisation
Vedic Lifesciences (India)

ROR
https://ror.org/00xd7fg81

Funder(s)

Funder type
Industry

Funder Name
Sierra Mountain Minerals, Inc. (Canada)

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	21/10/2005		Yes	No