

Oral cetylated fatty acid for the improvement of function, quality of life, and pain in patients with moderate to severe knee osteoarthritis

Submission date
14/07/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
08/08/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
29/10/2021

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

IX100

Study information

Scientific Title

Oral cetylated fatty acid for the improvement of function, quality of life, and pain in patients with moderate to severe knee osteoarthritis

Study objectives

To determine if oral cetylated fatty acid (Celadrin®) improves musculoskeletal performance, improves quality of life, and reduces pain and in patients with moderate to severe osteoarthritis of the knee.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Copernicus Group Institutional Review Board (CGIRB) on the 23rd January 2006 (ref: Tracking # MED4-05-237).

Study design

74-day randomised, double-blind, placebo-controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis of the knee

Interventions

Celadrin® (oral cetylated fatty acid) 1720 mg per day or placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cetylated fatty acid (Celadrin®)

Primary outcome(s)

Six-minute timed walk, assessed at baseline, 2, 4 and 8 weeks.

Key secondary outcome(s)

The following were assessed at baseline, 2, 4 and 8 weeks:

1. Pain Visual Analogue Scale (VAS)
2. Timed up and go test
3. Unilateral anterior reach
4. Western Ontario and McMaster Universities Osteoarthritic (WOMAC) index
5. Lequesne Algofunctional Index (LAI)
6. ROM

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Diagnosis of moderate to severe osteoarthritis of the knee by American College of Rheumatology (ACR) clinical criteria (95% sensitive and 69% specific)
2. Pain in the knee
3. At least three of the following:
 - 3.1. Age greater than or equal to 40 (note - original ACR Criteria call for age greater than 50)
 - 3.2. Morning stiffness lasting 30 minutes or less
 - 3.3. Demonstration of crepitus during knee Range Of Motion (ROM)
 - 3.4. Bony tenderness
 - 3.5. Bony enlargement
 - 3.6. No palpable warmth
4. Presence of knee pain greater than six months
5. Presence of knee pain for at least 10 days in the previous month
6. Subjects agree to stop all pain medications
7. Baby aspirin (81 mg) is allowed
8. Subject agrees to all study visits
9. Females of child bearing potential must agree to use appropriate birth control methods during the active study
10. Must agree not to initiate any new exercise or diet program during the study
11. Must agree not to change their current diet or exercise program

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

93

Key exclusion criteria

1. Rheumatoid arthritis or other autoimmune arthritis
2. Receipt of glucocorticoid injection or hyaluronic acid injection in affected knee within the last three months
3. Use of cetylated fatty acid within the 45 days prior to screening
4. Serious active medical conditions
5. Corticosteroids or other immunosuppressants
6. Current use of insulin or use of insulin in the past three months
7. Non-compliance during the run-in phase of the study
8. Cannot perform all of the required functional assessments
9. Subjects unable to understand or follow the study protocol
10. Subjects with known sensitivities to the ingredients in the product

11. Subjects with any cancer in the last five years (except non-melanoma skin cancer)
12. Subjects on anticoagulation therapy
13. Subjects with brain and/or spinal cord injury
14. Bed or wheelchair bound

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

United States of America

Study participating centre

18250 Roscoe Boulevard
Northridge
United States of America
91325

Sponsor information

Organisation

Imagenetix Inc. (USA)

Funder(s)

Funder type

Industry

Funder Name

Imagenetix Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results	Results (non peer reviewed) on funder website	20/01/2011	29/10/2021	No	No