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

Submission date	Recruitment status	[ ] Prospectively registered
14/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2021	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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) ont he 23rd January 2006 (ref: Tracking # MED4-05-237).

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

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

Secondary outcome measures
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 McMasters Universities Osteoarthritic (WOMAC) index
5. Lequesne Algofunctional Index (LAI)
6. ROM

Overall study start date
01/01/2006

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

Age group
Adult

Sex
Both

Target number of participants
80

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)

Sponsor details
16935 W. Bernardo Drive
San Diego
United States of America
92127

Sponsor type
Industry

Website
http://www.imagenetix.net/

Funder(s)

Funder type
Industry

Funder Name
Imagenetix Inc. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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