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The effect of cetylated fatty acid supplementation on low back pain

Submission date
05/04/2024

Recruitment status
No longer recruiting

Registration date
23/05/2024

Overall study status
Completed

Last Edited
24/07/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Low back pain is the leading contributor to disability in the U.S. with causes including degeneration of the spine, spinal stenosis, spondylolisthesis, and disc herniation. Current first-line treatment includes the use of NSAIDs to calm inflammation, however, these anti-inflammatories have demonstrated significant results alongside notable side effects of renal toxicity, GI side effects, and ulcers. Second-line treatment can extend to opioids in severe cases, which are not recommended due to patient dependence and addiction. Lastly, surgical interventions, such as spinal fusion and disc replacement, are last resort yet have high risks of complications, occurrence of pain, and continued use of NSAIDs despite intervention. Cetylated fatty acids (CFA) have been used to treat arthritis and sports injuries, mainly in hip, knee, and shoulder patients, as they are believed to reduce pain by decreasing the secretion of leukotriene B4 from stimulated neutrophils. There is an opportunity to apply CFA treatment to low back pain, in hopes of decreasing inflammation and providing a more optimal treatment for those who have adverse reactions to NSAIDs, opioids, or surgical intervention. This study aims to evaluate the effect of CFA supplementation on chronic, axial low back pain in patients over the age of 21 years old.

Who can participate?
Patients aged 21 years old and over with axial back pain from facet degenerative joint disease for more than 3 months will be recruited from a single center

What does the study involve?
Participants will take an oral supplementation two times a day and wear a patch for eight hours each day, over 30 days. Patients will fill out the questionnaires before and after taking the supplement to determine if CFAs ease back pain.

What are the possible benefits and risks of participating?
The benefits of participating in this trial include potential remission of low back pain symptoms such as stiffness, aching, and ambulation with a low side-effect profile supplement (i.e. cetylated fatty acids). The supplement has been shown to not induce adverse events such as GI ulcers, bleeding, or renal insufficiency, which can be found in mainstay treatment options, such as NSAIDs.

Documented risks of utilizing cetylated fatty acid supplementation include the potential for GI discomfort (flatulence, bloating), anaphylaxis, or skin irritation, as well as a patient not experiencing remission of symptoms.

Where is the study run from?
PharmaNutra Spa, Italy

When is the study starting and how long is it expected to run for?
April 2023 to December 2023

Who is funding the study?
PharmaNutra Spa, Italy

Who is the main contact?
Dr Vijay Vad, a Sports Medicine and PM&R physician at the Hospital for Special Surgeries, vadv@hss.org

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of cetylated fatty acid supplementation on low back facet joint arthritis

Study objectives
The Cetilar Back Pain System will act synergistically to reduce axial back pain from facet degenerative joint disease

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2023, Western Institutional Review Board (1019 39th Avenue SE Suite 120, Puyallup, WA, 98374, United States of America; +1 360-252-2500; clientservices@wirb.com), ref: 20230506

Study design
Prospective single-cohort study

Primary study design
Observational

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Remediating chronic axial discogenic back pain

Interventions

This is a prospective observational study with 25 treated patients over the age of 21 years old with remediating chronic axial discogenic back pain, where patients will apply the Cetilar Back Pain System in two groups:
1. Cetilar stick oral formulation (Cetylated Fatty Acid 800mg - 10 ml) twice daily
2. Cetilar Patch (8 hours duration) every day for 30 days to analyze the effects of Cetylated Fatty Acid on low back pain

Intervention Type
Supplement

Primary outcome(s)
Low back symptoms and pain measured using the Roland Morris Disability Questionnaire (RMDQ) pre-supplement and post-supplement after 30 days

Key secondary outcome(s))
The following secondary outcome measures are assessed pre- and post-supplement after 30 days:
1. Pain measured using the Numeric Pain Rating Scale (NPRS)
2. Adverse events measured using patient medical records at the end of the study
3. Treatment failure measured using patient medical records at the end of the study

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Aged 21 years old and over
2. Axial back pain from facet degenerative joint disease for more than 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
21 years

Upper age limit
100 years

Sex
All

Key exclusion criteria

1. Narcotic pain medication
2. Unwilling to follow study protocol
3. Pregnancy or currently breastfeeding
4. Low back pain from a traumatic injury
5. Currently using a pain patch (e.g lidocaine)

Date of first enrolment
01/06/2023

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
United States of America

Study participating centre
The Hospital for Special Surgery
523 East 72nd Street 9th Floor
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Sponsor information

Organisation
PharmaNutra S.p.A.

Funder(s)

Funder type
Industry

Funder Name
PharmaNutra S.p.A

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study will be available upon request from the primary investigator, Dr Vijay Vad, vadv@hss.org. Raw data will be coded to avoid the identification of patients. Consent was both required and obtained from all participants.

IPD sharing plan summary

Available on request