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Fatty acid dietary supplement for chronic low back pain

Submission date
26/04/2022

Recruitment status
No longer recruiting

Registration date
28/04/2022

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Approximately 8 out of 10 people worldwide will suffer from low back pain at some point in their life. Most of the episodes of low back pain resolve spontaneously, however, the subset of patients who continue to experience chronic symptoms is so large that it has been acknowledged as the most common cause of disability. Medical treatment for chronic low back pain consists of long-term use of anti-inflammatories and pain killers, that when used for long periods of time can cause severe adverse effects, injuring the stomach, liver, and kidneys. Cetylated fatty acids are a dietary supplement that has showed to decrease pain related to knee osteoarthritis as well as inflammatory markers in vitro. They are safe and rarely cause adverse effects when ingested for a long time. But there is no information regarding the effectiveness of cetylated fatty acids in improving pain and function related to low back pain. Therefore we have decided to conduct a pilot study to evaluate this.

The aim of this study is to evaluate the effectiveness of Cetylated Fatty Acids in reducing pain and improving function in patients with chronic lower back pain.

Who can participate?
Patients, both male and female, age 21 or older, suffering from low back pain for more than 3 months can participate in the study.

What does the study involve?
The study involves taking a dietary supplement that consists of Cetylated Fatty Acids for 1 month. Patients that participate in the study are going to be evaluated for pain and function using validated questionnaires, before starting the treatment and at the end of the month. Any adverse effects related to the dietary supplement are going to be evaluated and treated (if necessary) during the whole follow-up

What are the possible benefits and risks of participating?
The probable benefits of the dietary supplement are improving low back pain and decreasing disability related to the pain.

Risks of participating are rare, however, adverse effects related to the dietary supplement may occur. Some of these adverse effects may be allergic reactions, heartburn, nausea, vomiting, and diarrhea.

Where is the study run from?
The private practice of Dr Vijay B. Vad, New York City, NY, USA.

When is the study starting and how long is it expected to run for?
April 2022 to July 2022

Who is funding the study?
The Vad foundation, New York, NY, USA.

Who is the main contact?
Dr Antonio Madrazo-Ibarra, amadrazoi@live.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Vijay Vad

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effectiveness of cetylated fatty acids on pain and mobility in patients with chronic low back pain

Study objectives

A dietary supplement based on cetylate fatty acids will decrease pain and increase function in patients with chronic low back pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/28/2022, WCG Institutional Review Board (1019 39th Ave., SE, Suite 120, Puyallup, WA 98374; +1 855-818-2289; clientservices@wcgirb.com), ref: 20220202, study number: 13291166

Study design
Prospective interventional cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low back pain

Interventions
Patients with chronic low back pain will take 2 capsules twice a day of LipoCet (Cetylated Fatty Acids) 300mg for 1 month.

Intervention Type
Supplement

Primary outcome(s)
Patients' functionality based on the Oswestry Low Back Pain Disability Questionnaire (ODI) evaluated pre-treatment and after 1 month of initiating the dietary supplement.

Key secondary outcome(s))
1. Low back pain based on the Numeric Pain Rating Scale (0-10) evaluated pre-treatment and after 1 month of initiating the dietary supplement.
2. Adverse effects related to the dietary supplement evaluated after 1 month of the treatment using a questionnaire.

Completion date
30/07/2022

Eligibility

Key inclusion criteria
Patients over 21 years of age with low back pain for more than 3 months.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients currently on narcotic pain medication
2. Patients unwilling to follow the study protocol
3. Pregnant or currently breastfeeding
4. Patients with low back pain from a traumatic injury
5. Patients currently using a pain patch (e.g. lidocaine)

Date of first enrolment
01/05/2022

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Private practice of Dr. Vijay B. Vad
519 E 72nd St Suite 203
New York City
United States of America
10021

Sponsor information

Organisation
Vad Foundation

Funder(s)

Funder type
Charity

Funder Name
Vad Foundation

Results and Publications

Individual participant data (IPD) sharing plan
Raw data (coded to avoid identification of patients) will be shared with anyone upon request to the primary investigator.
vadv@hss.edu

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/02/2023	18/08/2023	Yes	No