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Innovations in the management of musculoskeletal pain with alpha-lipoic acid

Submission date
10/03/2016

Recruitment status
No longer recruiting

Registration date
15/03/2016

Overall study status
Completed

Last Edited
21/05/2021

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
Pain is a major problem affecting one-third of Canadians and costing $850 billion/year in North America alone. Fibromyalgia (FM) is a common long-term condition, which causes widespread muscle and joint pain all over the body. The exact cause of FM is unknown, but it is thought that a variety of physical, mental and emotional factors are responsible. FM is also common in elderly patients emphasizing the urgent need to improve treatment as the population ages. Current pain-relieving medications (analgesics) used provide incomplete relief and disabling side effects such as tiredness and mental slowing – already prominent in people suffering from FM, and the elderly. Alpha-lipoic acid (ALA) is an antioxidant which has proven effective in the treatment of neuropathic pain (pain caused by nerve damage) with minimal side effects. ALA could potentially be an effective treatment for FM, as it does not make existing symptoms, such as tiredness and mental slowing, worse. The aim of this study is to test the effectiveness of ALA in treating pain in FM.

Who can participate?
Adults with fibromyalgia who have experienced at least moderate pain for at least three months.

What does the study involve?
Participants are randomly allocated to one of two groups who receive the two treatments in a different order. One treatment involves receiving the study medication (ALA) by mouth, three times a day for four weeks. The other treatment involves taking an identical looking placebo (dummy pill) by mouth, three times a day for four weeks. Each of the treatment periods will consist of three weeks of gradual dose increase, a week taking the maximal dose treatment (week four) and a 'washout' week when no study medication is taken at all (week five). Participants in both groups are interviewed by telephone every week in order to find out if the medication has had an effect on their pain intensity.

What are the possible benefits and risks of participating?
Participants may possibly benefit from pain reduction after taking the ALA. There is a small risk that participants may experience unwanted side effects from the ALA, including nausea and vomiting, headache and vertigo (spinning sensation when still).

Where is the study run from?
Providence Care, Kingston (Canada)

When is the study starting and how long is it expected to run for?
November 2015 to December 2018

Who is funding the study?
Physicians Services Incorporated Foundation (Canada)

Who is the main contact?
Dr Ian Gilron

Contact information

Type(s)
Scientific

Contact name
Dr Ian Gilron

Contact details
Kingston General Hospital
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Additional identifiers

Protocol serial number
ANAE-287-15

Study information

Scientific Title
Double-blind, randomized, placebo-controlled trial of alpha-lipoic acid for fibromyalgia

Acronym
IMPALA

Study objectives
Alpha-lipoic acid is safe and superior to placebo in treating pain in fibromyalgia.

Ethics approval required
Old ethics approval format

Ethics approval(s)

The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, 03/12/2015, ref: ROMEO/TRAQ #6016602

Study design
Single-center prospective interventional double-blind randomized placebo-controlled crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
Participants are randomly allocated to one of two groups by the research pharmacist using a computer-generated randomization code.

Group 1: Participants are treated with alpha-lipoic acid 600 mg orally three times daily for four weeks, followed by one week washout period. The participants then take an identical looking placebo three times daily for four weeks.

Group 2: Participants are treated with a placebo orally three times daily for four weeks, followed by one week washout period. The participants then take alpha-lipoic acid 600 mg three times daily for four weeks.

Participants in both groups are contacted weekly by telephone to measure pain intensity.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Alpha-lipoic acid

Primary outcome(s)
Pain intensity is measured using mean daily “average” pain intensity at maximal tolerated dose, of each period is determined by averaging the daily pain intensity, as measured using the 0-10 Numerical Rating Scale over the 7 days of week 4 of each treatment period (alpha-lipoic acid and placebo).

Key secondary outcome(s))
1. Adverse effects are measured using ratings of frequency and severity of treatment-emergent adverse effects weekly throughout the study
2. Fibromyalgia pain impact is measured using the fibromyalgia Impact Questionnaire at 4 and 9 weeks

3. Sleep quality is measured using the Medical Outcomes Study Sleep Scale at 4 and 9 weeks
4. Global treatment response is measured using the Patient Global Impression of Change at 4 and 9 weeks
5. Fibromyalgia pain impact is measured using the Brief Pain Inventory at 4 and 9 weeks
6. Mood is measured using the Beck Depression Inventory-2 at 4 and 9 weeks
7. Anxiety is measured using the Beck Anxiety Inventory at 4 and 9 weeks
8. Pain quality descriptors are measured using the short form McGill Pain Questionnaire at 4 and 9 weeks
9. Quality of life is measured using the SF-36 survey at 4 and 9 weeks
10. Quality of treatment blinding is measured using a blinding questionnaire at 4 and 9 weeks
11. Acetaminophen consumption is measured using a daily diary at 4 and 9 weeks

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Aged 18 and older
2. Meeting the 2010 American College of Rheumatology diagnostic criteria for fibromyalgia
3. Experienced at least moderate daily pain (Numerical Rating Scale ≥ 4/10) for at least 3 months prior to study entry
4. AST (aspartate aminotransferase)/ALT (alanine aminotransferase) no greater than 20% the upper limit of normal
5. Serum creatinine no greater than 50% the upper limit of normal
6. Necessary abilities, visual acuity and language skills for pain diary completion and telephone communication with study nurses

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
27

Key exclusion criteria
1. Any major organ system disease
2. Major poorly controlled psychiatric disorder
3. Severe depression or suicidal ideation

4. Active substance abuse disorder
5. Lactose intolerance
6. Hypersensitivity to ALA
7. Painful condition more than 50% as severe as their fibromyalgia pain
8. Unwillingness to use a highly effective form of contraception (women of childbearing potential)

Date of first enrolment
01/07/2016

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
Canada

Study participating centre
Providence Care
St. Mary's of the Lake Hospital
340 Union Street
Kingston
Canada
K7L 5A2

Sponsor information

Organisation
Physicians Services Incorporated Foundation

ROR
https://ror.org/0385yzn06

Funder(s)

Funder type
Research organisation

Funder Name
Physicians' Services Incorporated Foundation

Alternative Name(s)
PSI Foundation, PSI

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/03/2017		Yes	No
Results article		01/02/2021	21/05/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes