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Testing the effectiveness and safety of alpha-lipoic acid for pain reduction

Submission date
27/05/2021

Recruitment status
No longer recruiting

Registration date
21/06/2021

Overall study status
Completed

Last Edited
08/02/2022

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
α-lipoic acid (ALA) is a substance produced by the human gut with antioxidant and anti-inflammatory activities. ALA can also decrease blood sugar levels in patients with high blood sugar.
Clinical studies have found that ALA has a beneficial effect in patients suffering from different kinds of acute and chronic pain. Its safety was also demonstrated in pregnant women. Other clinical trials reported infrequent adverse effects such as allergic skin reactions, gastrointestinal symptoms and dizziness.
The aim of this study is to evaluate the effectiveness of ALA treatment, taken orally, at reducing different kinds of acute and chronic pain at two doses (800 and 400 mg/day).

Who can participate?
Patients aged 18-75 years with arthralgia (joint pain), primitive neuropathic pain or idiopathic myalgia (muscle pain), who cannot or do not want to take analgesic (painkiller) drugs, who have fasting blood sugar levels below 110 mg/dl

What does the study involve?
Participants are randomly allocated into three groups to take a daily dose of 800 mg/day of ALA (two tablets of 400 mg), 400 mg/day of ALA (one tablet of ALA and one tablet of placebo), or placebo (two tablets of placebo) for 2 months. Pain and blood sugar levels are measured at the start of the study and after 2 months.

What are the possible benefits and risks of participating?
Participants should have a benefit regarding pain. Participants will be continuously monitored and their liver and kidney function assessed.

Where is the study run from?
Comegen, Naples (Italy)

When is the study starting and how long is it expected to run for?
September 2020 to July 2021

Who is funding the study?
Italian Association of Health Products and Manufacturers - Federsalus (Italy)

Who is the main contact?
1. Prof. Maria Daglia (scientific)
maria.daglia@unina.it
2. Dr Cristina Esposito (public)
cristina.esposito@unina.it

Contact information

Type(s)
Scientific

Contact name
Prof Maria Daglia

ORCID ID
http://orcid.org/0000-0002-4870-7713

Contact details
Università degli Studi di Napoli Federico II Domenico
Montesano Street, 49
Naples
Italy
80131
+39 (0)3331703492
maria.daglia@unina.it

Type(s)
Public

Contact name
Dr Cristina Esposito

Contact details
Università degli Studi di Napoli Federico II
Domenico Montesano street, 49
Naples
Italy
80034
+39 (0)81678644
cristina.esposito@unina.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ALA121

Study information

Scientific Title
Study on the efficacy and safety of an oral α-lipoic acid food supplement in the reduction of pain in different clinical settings: a monocentric, randomized, double-blind, placebo-controlled clinical trial

Acronym
ALAES

Study objectives
The outcome of the study is to evaluate the efficacy and safety of α-lipoic acid (ALA) administration to normoglycaemic (or with a mild dysglycaemia) subjects with primary neuropathic pain, idiopathic myalgia or arthralgia, who cannot or do not want to take analgesic drugs (non-steroidal anti-inflammatory drugs).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/11/2020, ASL Napoli 1 Centro Ethics Committee (Via Comunale del Principe, 13/A, 80145, Napoli, Italy; +39 (0)812544495; comitatoetico@aslnapoli1centro.it), ref: 532/C.E 16/2020

Study design
Interventional monocentric randomized double-blind placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied

Pain in different clinical settings (e.g. arthralgia, primitive neuropathic pain, idiopathic myalgia etc), fasting glycemia below 110 mg/dl

Interventions

The randomization sequence was generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) and the randomization list was kept hidden. The participants were assigned to each of the three treatment groups (ALA 800 mg/day), ALA (400 mg/day) and placebo casually and by simple randomisation (1:1:1 allocation ratio). The randomization code will consist of a three-digit number as indicated in the respective Case Report Form (CRF).

In the clinical study 210 participants were enrolled and divided into three groups (70 for each group):
Group 1: 800 mg/day of ALA (two tablets of 400 mg) to confirm the efficacy and safety
Group 2: 400 mg/day of ALA (one tablet of ALA and one tablet of placebo), to confirm whether the minimal dose is potentially effective
Group 3: placebo (two tablets of placebo)

Participants underwent two visits (baseline = t0 and after 2 months = t1) in an outpatient setting. After each clinical visit, all data are filled in the CRF by physicians. In detail, the data acquired are:

Baseline visit (t0): information on the sociodemographic, clinical and symptomatologic characteristics of the participants; numerical rating scale (NRS) and visual analogue scale (VAS) results; fasting blood glucose assessment; renal and hepatic toxicity assessment by blood test for the evaluation of creatinine level, alanine aminotransferase (ALT) and aspartate aminotransferase (AST).

After 2 months (t1): assessment of possible adverse reaction after the ingestion of the food supplement by a specific form based on the one used by the Italian Phytovigilance System (IPS), National Institute of Health; numerical rating scale (NRS) and visual analogue scale (VAS) results; fasting blood glucose assessment; renal and hepatic toxicity assessment by blood test for the evaluation of creatinine level, alanine aminotransferase (ALT) and aspartate aminotransferase (AST).

Intervention Type

Supplement

Primary outcome measure

1. Pain measured using the Numerical Rating Scale (NRS) and the Visual Analogue Scale (VAS) at baseline (t0) and after 2 months (t1)
2. Fasting blood glucose in normoglycemic or mildly dysglycaemic subjects measured by taking a blood sample from participants who have fasted for at least 8 hours, at t0 and t1

Secondary outcome measures

1. Possible hepatic and renal toxicity resulting from oral administration of ALA by the evaluation of creatinine level, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) assessed by blood test at t0 and t2
2. Possible adverse reactions using a form specifically prepared according to the Italian Phytovigilance System (IPS) at t0 and t2

Overall study start date
09/09/2020

Completion date
30/07/2021

Eligibility

Key inclusion criteria
1. Patients of both sexes aged 18-75 years
2. Have arthralgia, primitive neuropathic pain, or idiopathic myalgia
3. Cannot or do not want to take analgesic drugs (non-steroidal anti-inflammatory drugs)
4. Fasting glycemia below 110 mg/dl
5. Signed informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
210

Total final enrolment
210

Key exclusion criteria
1. Pregnant women
2. Women suspected of being pregnant
3. Women who hope to become pregnant
4. Breastfeeding women
5. Patients with allergies
6. Congenital or acquired immunodeficiency syndrome
7. Fasting glycaemia above 110 mg/dl
8. Obese (body mass index >30 kg/m^2)
9. Taking pharmacological therapy for diabetes, cardiovascular diseases, systemic chronic disease, or analgesic, anti-inflammatory or food supplements for the pain
10. Considered unsuitable for participation by the physician

Date of first enrolment

27/05/2021

Date of final enrolment
10/06/2021

Locations

Countries of recruitment
Italy

Study participating centre
Comegen
Viale Maria Bakunin 41
Naples
Italy
80126

Sponsor information

Organisation
Italian Association of Health Products and Manufacturers - Federsalus

Sponsor details
Via Brenta, 2/A
Roma
Italy
00144
+39 (0)6 54 221 967
federsalus@federsalus.it

Sponsor type
Industry

Website
https://www.federsalus.it/

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
08/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Piccinocchi Gaetano (piccinocchi.gaetano@simg.it).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			08/07/2021	No	Yes
Protocol file			08/07/2021	No	No
Results article		12/10/2021	08/02/2022	Yes	No