ISRCTN86507492 https://doi.org/10.1186/ISRCTN86507492

Testing a food supplement in improving strength, power and mental alertness

Submission date 14/11/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/11/2022	**Overall study status** Completed	
Last Edited 14/11/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The aim of the study is to assess the effect of a food supplement in providing physical energy in a short time (immediate energy) and in improving attention/concentration, without giving the typical effects of caffeine on heart rate and sleep disturbance. The test product is a food supplement based on L-carnitine. L-carnitine, and carnitine in general, is a key component in creating energy for the cells. Its main function, helping break down fatty acids for use as energy, keeps the body's cells powered and working efficiently.

Who can participate?
Adults male and female subjects aged between 18 and 60 years old

What does the study involve?
Participants will be asked to attend clinic visits at screening, at baseline and after 1, 3 and 10 product intakes. During the screening visit, the medical doctor will inform the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent will be enrolled in the study. All the measurements/assessments will be carried out using minimally invasive procedures. The total duration of each visit will be 30 minutes. The study duration will be 10 days with intermediate checks at 1 and 3 days.

What are the possible benefits and risks of participating?
The potential benefits due to product use are related to an improvement of physical energy during endurance and to an improvement of attention/concentration in the short term (after 1 product intake).

The product is manufactured according to the applicable national and international rules and regulations. All ingredients included in the product formula are approved for use in food/food supplements. The potential risks associated with the use of the product are related to both subjective and objective adverse events (AEs) (e.g., bloating, diarrhea, stomachache). The occurrence of AEs related to individual susceptibility to specific ingredients in the product could be related to the biological phenomenon that is not avoidable and cannot be considered as AEs due to product intake. Potential risks are assumed to be mild to moderate and are not expected to pose a risk to human health. Risks associated with the procedures involved in this study are

judged as minor. All the measurements carried out will not be invasive and no side effects are expected from the measurement process except for blood withdrawal. Bleeding, bruising, lightheadedness (especially after donating blood), rash, skin irritation from tape or adhesive from an applied bandage, and soreness can be experienced after blood withdrawal.

Where is the study run from?
Farmaceutici Procemsa S.p.A. (Italy)

When is the study starting and how long is it expected to run for?
October 2022 to January 2023

Who is funding the study?
Farmaceutici Procemsa S.p.A. (Italy)

Who is the main contact?
Vincenzo Nobile, vincenzo.nobile@complifegroup.com

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
IT0005076/22 Version N.01 09/11/2022

Study information

Scientific Title
Clinical trial for the evaluation of the efficacy of a food supplement in improving of strength, power and mental alertness

Acronym
LCAR

Study objectives
There will be positive acute effects of a dietary drinkable food supplement on physical performance (including strength and power) and on cognitive attention in adult subjects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/11/2022, Independent Ethics Committee for Non-Pharmacological Clinical Investigations [Comitato etico indipendente per le indagini cliniche non farmacologiche] (Via XX Settembre 30/4 - 16121 Genova, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2022/06

Primary study design
Interventional

Study design
Single-center randomized double-blind placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy volunteer

Interventions
The product under study consists of a food supplement based on L-Carnitine. The product is aimed to provide physical energy in a short time (immediate energy) and attention /concentration, without giving the typical effects of caffeine on heart rate and sleep disturbance.

A restricted randomization list (“Wey’s urn” algorithm) will be generated by the in-site Study Director. An independent technician will dispense either the active or the placebo products according to the randomization list. The study will adhere to establish procedures to maintain separation between the investigator and its collaborators and the staff that will deliver the intervention. The investigator and their collaborators who will obtain outcome measurements will be not informed on the product group assignment. Staff who will deliver the intervention will not take outcome measurements. Subjects, investigators and collaborators will be kept

masked to the product assignment. Products will be supplied in the same packaging without any obvious differences among products.

Intervention Type
Supplement

Primary outcome(s)
The following outcome will be measured at baseline and after 90 minutes after 1 and 3 product intake:
1. Weight measured using scales
2. Body mass index measured using scales for weight measurement and a meter for height measurement
3. Endurance strength measured by a Chest press “repetitions to failure” test (70 % - 1 repetition maximum [1RM]) followed by a Leg press “repetitions to failure” test (70 % - 1RM) after a 15 minutes rest period
4. Muscle power measured by 30 ‘’ arms Wingate Anaerobic Power Test (aWAnT) followed by 30 ‘’ legs Wingate Anaerobic Power Test (lWAnT) after a 15 minutes rest period

The following outcome will be measured at baseline and after 90 minutes after 1 product intake:
5. Cognitive assessment measured by the Mini-Mental State Examination (MMSE) questionnaire

Key secondary outcome(s)
Product safety outcomes will be measured at baseline and after 1, 3, and 10 product intake:
1. Heart rate measured using a sphygmomanometer
2. Blood pressure measured using a sphygmomanometer
3. Electrocardiogram (ECG) measured using an electrocardiograph

Completion date
31/01/2023

Eligibility

Key inclusion criteria
Healthy male and female subjects,
Age between 18 and 60 (extremes included) years old,
Subjects with waist circumference ≤ 97 cm and BMI<28
1. Subject is in good health and appropriate for exercise as determined by physical examination, medical history
2. The eligible subjects will be recruited for the study after examination and the establishment of a basic level of parameters. Score ≥ 24 on the Mini-Mental State Examination (MMSE)
3. Non-smoker
4. Subject agrees not to use any food supplement until study completion
5. Subject avoiding consumption of any food supplement (for pre-workout / memory improving drugs or food supplements that can interfere with the CNS activity) for at least 4 weeks prior to the study start
6. Subjects willing to avoid caffeine and alcohol assumption for the 24 hours prior to the test visits
7. Subjects who have not been recently involved in any other similar study (at least one month of wash-out),
8. Willingness to not vary the normal diet and daily routine (at the beginning of the study volunteers will list their usual routine: sports activities, sleeping habits, etc.)

9. Reading, understanding and signing approval of the informative consent
10. Available and willing to follow the procedure of the study protocol
11. Subjects registered with National Health Service (NHS)
12. Subjects certifying the truthfulness of the personal data disclosed to the investigator

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subject does not meet the inclusion criteria
2. Subject with known or suspected food intolerance or food allergy
3. Any condition that the principal investigator deems inappropriate for participation
4. Us of pharmacological treatments known to interfere with the subject's metabolism /physiology
5. Severe concurrent diseases
6. Having a diagnosed chronic disease (blood, cardio-vascular, psychiatric, neuro-degenerative, diabetes, cancer, liver, gastric, skin, kidney etc.) and/or under medical treatment
7. Adult protected by the law (under guardianship, or hospitalized in a public or private institution, for a reason other than the research, or incarcerated)
8. Subject is unable to communicate or cooperate with the Investigator due to language problems, poor mental development, or impaired cerebral function
9. Clinical history with the presence of any relevant disorder or administration of drugs/food supplements that can potentially interfere with the treatment under study
10. Subjects with a history of drug, alcohol and other substance abuse
11. Subjects with active cancers or on chemotherapy
12. Other factors that limit their ability to cooperate during the study
13. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)
14. Subjects not able to be contacted in case of emergency

Date of first enrolment
28/11/2022

Date of final enrolment
02/12/2022

Locations

Countries of recruitment
Italy

Study participating centre
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87036

Sponsor information

Organisation
Farmaceutici Procemsa S.p.A.

Funder(s)

Funder type
Industry

Funder Name
Farmaceutici Procemsa S.p.A.

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored on the Complife Italia server. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer’s management software. The code is composed of a letter, four digits, and a letter. Access to the study's raw data is allowed by application only to the study director and the person designated by him to elaborate on the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and inferential analysis (data normality and statistical test).

IPD sharing plan summary
Stored in non-publicly available repository