A Randomized, Double-blind, Placebo-controlled study to investigate the efficacy of oleuropein on skeletal muscle energy metabolism and fatigue in humans

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The objective of this exploratory trial is to explore the acute and chronic effects of daily olive leaf extract supplementation on muscle energy and fatigue in healthy male adults

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50903

Source
ToetsingOnline

Brief title
Oleuropein and muscle energy metabolism

Condition

- Other condition

Synonym
Muscle energy metabolism, Muscle energy utilization

Health condition

This study will evaluate the effects of oleuropein supplementation on muscle energy metabolism and fatigue

Research involving
Human

Sponsors and support

Primary sponsor: Société des Produits Nestlé SA
Source(s) of monetary or material Support: Ministerie van OC&W,Société des Produits Nestlé SA

Intervention

Keyword: Muscle energy metabolism, Muscle fatigue, Oleuropein

Outcome measures

Primary outcome

This is an exploratory trial with no formal primary or secondary outcomes

Secondary outcome

This is an exploratory trial with no formal primary or secondary outcomes

Study description

Background summary

During aging, changes occur in our muscles. Among others, the muscles become weaker and are more easily fatigued. These differences eventually could lead to a decrease in functional capacity. Recently, an extract from olive leaves has been discovered to improve muscle energy metabolism and thereby reducing muscle fatigue in animal studies. However, whether this supplement would also be effective in humans is not yet known.

Study objective

The objective of this exploratory trial is to explore the acute and chronic effects of daily olive leaf extract supplementation on muscle energy and fatigue in healthy male adults

Study design

Parallel design, randomized, dubble-blind

Intervention

Participants will undergo a screening session, baseline measurement, and 4 test days. The first 2 test days will be performed at the beginning of the study in order to evaluate the acute effects of the supplement. The last 2 test days will be performed at the end of the research period, in order to evaluate the prolonged effect of supplement ingestion.

Study burden and risks

The burden and risks involved in participating in this experiment are small. Participants will visit the University on six occasions (screening + 1 familiarization + 4 Test Days). The first visit will involve a screening visit (~2 h), during which the eligibility of the participant will be assessed. During the screening visit, a medical questionnaire will be filled out, a fasted blood sample will be obtained.
During the study, participants will perform a maximal strenght test and a muscle fatigue test on a Biodex dynamometer on several occasions, which results in acute muscle fatigue and may result in muscle soreness, comparable to performing leg exercises at the gym. The subjects will undergo a full body MRI scan. An MRI scan is non-invasive and safety is guaranteed by excluding participants with MRI contra-indications. Blood samples will be taken trhoughout the study with the only risk of a small local hematoma. Furthermore, the respiratory exchange ratio (RER) will be assessed by a ventilated hood (indirect calorimetry) which does not impose health risks. Muscle biopsies will be obtained under local anaesthesia by an experienced physician that may cause some minor discomfort. The discomfort is comparable to muscle soreness or the pain one has after bumping into the corner of a table. The Olive leaf extract supplement is cleared for human consumption and is commercially available. The recommended daily allowance is not exceeded during this study. For each visit, participants are required to come to the university in a fasted state, not having consumed any food or beverages (except for water) from 22:00 the evening before. There is no direct benefit of participation in this study for the participants, other than their contribution to scientific knowledge.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male
2. 50 to 70 years old
3. BMI 18.5-29.9 kg/m2
4. Healthy
5. Having given informed consent

Exclusion criteria

1. Allergy/intolerance to the study product
2. >5% body mass change in the previous 3 months
3. HbA1c * 6.5%
4. Blood pressure: systolic/diastolic >140/ and >90 mmHg (when both conditions are met)
5. Participating in a structured (progressive) exercise program
6. Smoking
7. Diagnosed acute or chronic medical conditions that, could impact study outcomes
8. Diagnosed musculoskeletal disorders
9. Chronic use of gastric acid suppressing medication
10. Unauthorized concomitant medications such as calcium antagonists (e.g. valproate), oral corticosteroids, anything that will prevent subjects from

safely completing the study according to the investigator or medications / drugs known interfering with the expected mechanism of action of IP or to affect the outcome parameters
11. Alcohol (intake higher than 3 servings per day. One serving is 0.4 dl of alcohol, 1 dl of wine, or 3 dl of beer) or drug abuse
12. Overly imbalanced or restrictive diet (e.g. hyperproteic, vegan, ketogenic, etc.)
13. Subjects not willing and/or not able to comply with scheduled visits and the requirements of the study protocol
14. Any implants that would be a contra-indication for performing an MRI scan.
15. Participation in another study at the same time
16. Blood donnation in the previous 2 months
17. Non-Dutch speaking

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	15-10-2021
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77527.068.21
Other	Protocol will be registered at ClinicalTrials.gov after approval by the METC