RAR-CLA and cognition

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29637

Source
Nationaal Trial Register

Brief title
CoRA

Health condition

cognitive impairment

Sponsors and support

Primary sponsor: Stepan Specialty Products B.V.
Source(s) of monetary or material Support: Stepan Specialty Products B.V.

Intervention

Outcome measures

Primary outcome

Episodic memory as measured with the RAVLT

Secondary outcome

cognitive functioning (episodic and working memory, attention, executive functioning, and psychomotor speed) as measured with a battery of cognitive tests, the evaluation of rumenic acid supplementation on anxiety, depressive symptoms, quality of life (measured with

questionnaires), and plasma fatty acid status (measured in blood)

Study description

Background summary

Objective: The primary objective is to investigate the effect of 12 weeks of supplementation with 3.5g/day of rumenic acid on cognitive functioning in older men and women at risk of cognitive impairment. Secondary objectives include the assessment of the effect of rumenic acid supplementation on mental well-being, handgrip strength, hand joint discomfort, and plasma fatty acid levels.
Study design: Randomized, parallel, double-blind, placebo-controlled trial.
Study population: Elderly (≥ 65 years, n=52) at risk of cognitive impairment.
Intervention: Subjects will receive a daily dose of 3.5g rumenic acid divided over six capsules (intervention) or six placebo capsules (control).
Main study parameters/endpoints: The primary study parameter is episodic memory as measured with the RAVLT. Secondary parameters entail cognitive functioning (episodic and working memory, attention, executive functioning, and psychomotor speed) as measured with a battery of cognitive tests, the evaluation of rumenic acid supplementation on anxiety, depressive symptoms, quality of life (measured with questionnaires), and plasma fatty acid status (measured in blood).

Study objective

Daily supplementation of 3.5g RAR-CLA will slow down cognitive decline as compared to placebo

Study design

0 weeks and 12 weeks

Intervention

Subjects will receive a daily dose of 3.5g rumenic acid divided over six capsules (intervention) or six placebo capsules (control).

Contacts

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Eligibility criteria

Inclusion criteria

• Aged ≥65 years
• At risk of cognitive impairment/ memory complaints
• Able to understand and perform the study procedures

Exclusion criteria

• Body Mass Index (BMI) >35 kg/m2
• Current use of medication belonging to the “sartans” or “glitazones”
• Current use of >500 mg/day of acetylsalicylic acid
• Current use of medication that affects inflammation (anti-inflammatory medication)
• Fish consumption of more than 1 serving per week
• Current or recent (<1 month) use of fish oil supplements
• Current or recent (<1 month) use of anti-inflammatory dietary supplements such as quercetin, curcumin, resveratrol, and/or other flavonoids
• Diabetes mellitus
• Having a disease which interferes with the effect of the RAR-CLA supplement and/or with the outcome measure (cognitive functioning) as judged by medical doctor
• Swallowing problems
• Current participation in other scientific research with the exception of EetMeetWeet!

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	02-09-2019
Enrollment:	52
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-03-2019
Application type:	First submission

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
NTR-new	NL7598
Other	METC-WU : 18/27

Study results