Vegan Diets: the short-term effects on daily muscle protein synthesis rates as compared to omnivorous diets inOlder adults assessed by D2O.

Published: 02-11-2022
Last updated: 07-04-2024

To investigate the short-term effect of a vegan diet on daily muscle fractional synthesis rates in comparison to an omnivorous diet in community-dwelling older adults.

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

Summary

ID

NL-OMON51669

Source
ToetsingOnline

Brief title
VD2O-study

Condition

- Other condition
- Appetite and general nutritional disorders
- Muscle disorders

Synonym
age-related muscle loss, Sarcopenia

Health condition

glucose- en lipidenmetabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Rijksoverheid

Intervention

Keyword: Aging, Muscle, Protein, Vegan

Outcome measures

Primary outcome

The primary study parameter includes the difference in muscle fractional

synthesis rates (FSR; %/day) between the vegan diet and omnivorous diet.

Secondary outcome

Secondary study parameters include the difference in satiety, blood pressure,

plasma blood glucose, insulin and lipid profile (HDL; LDL; cholesterol;

triglycerides) between the vegan and the omnivorous diet.

Study description

Background summary

A major cause of global environmental change is food production, with animal based food products having the greatest impact on the environment. Therefore, consumers are increasingly encouraged to consume more plant-based foods and lower their consumption of foods from animal origin. However, the consequences of such a transition on muscle mass still remains to be explored. This is of particular importance in the older population, where sarcopenia is highly prevalent. Sarcopenia is referred to as the age-related loss of lean mass and physical functioning, and begins approximately in the fifth decade of life. Adequate dietary intake, specifically protein intake, is a well-known strategy in counteracting sarcopenia in older adults. Plant-based foods are currently considered to be inferior to animal-based foods in their protein quality, suggesting that a diet fully consisting of plant-based foods (vegan diet) may

be suboptimal for the preservation of muscle mass in older adults. Current evidence regarding the anabolic properties of vegan diets is scarce.

Study objective

To investigate the short-term effect of a vegan diet on daily muscle fractional synthesis rates in comparison to an omnivorous diet in community-dwelling older adults.

Study design

A randomized controlled cross-over study.

Intervention

The intervention will be a fully controlled vegan diet with a duration of 10 days and will be compared to a fully controlled omnivorous diet with the same duration. Participants will be randomized to the order in which they consume the diets.

Study burden and risks

The risks of the study are minimal and acceptable. All products in the diets are commercially available. The short duration of the vegan diet excludes the possible risks of fractures, muscle wasting and vitamin B12 deficiency. Methods used to explore the effects have been widely used in other studies and will be performed according to SOPs. No side effects have been previously observed following the deuterated water protocol that will be used in this study. Venepuncture and muscle biopsies will be performed by the trained research physician and may cause some discomfort, but further risks are minor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Aged 65-79 years
Community-dwelling
Body Mass Index (BMI) 20-35 kg/m2

Exclusion criteria

- Following a vegetarian or vegan diet during the six months prior to the study;
- Following a diet that affects protein intake during the six months prior to the study;
- >=5% of body weight loss during three months before the start of the study;
- Participating in a structured exercise training program in the past 3 months;
- Being diagnosed with one of the following: diabetes; renal disease; neurological or neuromuscular disorders;serious cardiovascular diseases; cancer; chronic obstructive lung disease (COPD);
- Chronic use of medication that affects muscle function, e.g. corticosteroids, metformin, insulin;
- The use of the following medicines: acenocoumarol (sintrom); phenprocoumon (marcoumar); dabigatran(pradaxa); apixaban (eliquis); rivaroxaban (xarelto); clopidogrel (plavix); combination of acetylsalicylic acid orcarbasalate calcium (ascal) with dipyridamole.
- Allergic or intolerant to any product included in the diets;
- Not willing to stop nutritional supplements, with the exception of supplements on medical advice, and vitamin D;
- Not willing or afraid to give blood or undergo a muscle biopsy during the study;
- Unwilling to eat a vegan and an omnivorous diet for ten days each;

- Currently a research subject in another trial or participated in a clinical trial during 3 months before the start ofthe measurement period;
- Not being able to understand Dutch;
- Not having a general physician.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2022
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL82653.028.22
Other	NL9542