

The effect of a 2-week preoperative vegan diet versus omnivorous diet on the protein turnover in the osteoarthritic knee

Published: 05-02-2024

Last updated: 30-01-2025

Primary: To assess the effects of a 2-week preoperative vegan diet in comparison to an omnivorous diet on protein synthesis rates in Hoffa's fat pad, synovium, bone, ligaments, menisci, and cartilage in older adults with knee osteoarthritis...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON56530

Source

ToetsingOnline

Brief title

KneeT-vegan

Condition

- Tendon, ligament and cartilage disorders

Synonym

knee wear and tear, osteoarthritis in the knee

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Jaap Schouten Foundation

Intervention

Keyword: Knee, Musculoskeletal tissues, Protein synthesis, Vegan

Outcome measures

Primary outcome

Primary study parameters are protein synthesis rates of Hoffa's fat pad, synovium, bone, ligament, menisci, and cartilage.

Secondary outcome

Secondary parameters include blood pressure, and plasma amino acids.

Study description

Background summary

Protein from plant-based foods may be unable to stimulate protein synthesis due to a suboptimal essential amino acid content and a lower digestibility. However, a more optimal amino acid profile may be achieved by increasing portions sizes and blending multiple plant-based sources. Studies investigating the anabolic properties of vegan diets (total elimination of animal-based foods) rather than single plant-based foods in older adults are scarce. It remains unknown if a vegan diet can also affect protein synthesis rates in other musculoskeletal tissues than muscle.

Study objective

Primary: To assess the effects of a 2-week preoperative vegan diet in comparison to an omnivorous diet on protein synthesis rates in Hoffa's fat pad, synovium, bone, ligaments, menisci, and cartilage in older adults with knee osteoarthritis undergoing total knee arthroplasty.

Secondary: To assess the effects of a 2-week preoperative vegan diet in comparison to an omnivorous diet on blood pressure, and plasma amino acids in older adults with knee osteoarthritis undergoing total knee arthroplasty.

Study design

Multi-center, randomized, controlled trial with an intervention and a control group.

Intervention

Controlled vegan diet versus controlled omnivorous diet, both for a duration of 14 days.

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 standard operating procedures. No serious side effects have been previously observed following the deuterated water protocol that will be used in this study. Venipuncture will be performed by trained professionals and may cause some discomfort, but further risks are minor. Tissue collection will be performed during the surgical procedure. Since a plant-based diet is increasingly promoted, scientific evidence is necessary to assess the effects of such a diet on health outcomes.

Contacts

Public

Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL

Scientific

Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

- Written informed consent;
- Male and female patients scheduled for total knee arthroplasty;
- BMI between 20-32 kg/m²;
- Aged 60 - 80 years;
- Mentally competent, as judged by the treating physician.

Exclusion criteria

- Following a vegetarian or vegan diet or a diet that affects protein intake during the six months prior to the study;
- Participating in a structured exercise training program in the past three months;
- Lost more than 4 kg body weight during three months prior to the study;
- Chronic use of medications that affect protein metabolism (i.e. systemic corticosteroids, or prescription strength acne medications);
- Being diagnosed with one of the following: diabetes mellitus, rheumatoid arthritis, peripheral artery disease Fontaine III or IV, COPD GOLD III or IV, phenylketonuria, collagen disorders (e.g. Marfan and Ehler-Danlos);
- Receiving neoadjuvant chemotherapy or radiotherapy;
- Alcohol abuse (for men 15 or more alcoholic drinks per week and for women 8 or more alcoholic drinks per week);
- Surgical intervention to the knee in the past four weeks;
- Total parenteral nutrition at day of surgery;
- Glomerular filtration rate (GFR) <20 mL/min/1.73 m²;
- Allergic or intolerant to any product included in the diets;
- Osteoarthritis of the knee secondary to septic arthritis, osteonecrosis, fracture, osteochondritis dissecans, or malignant processes;
- Any other medical condition that may interfere with the safety of the participants or the outcome parameters, in the investigators judgement;
- Not willing to stop nutritional supplements, with the exception of vitamin D and supplements on medical advice.
- Investigator*s uncertainty about the willingness or ability of the participant to comply with the protocol instructions;
- Participation in other studies that may have an impact on the outcomes during the three months before the start of the current study.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	22-10-2024
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No
---------------	----

Ethics review

Approved WMO	
Date:	05-02-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	21-05-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL85073.091.23
Other	Volgt