Protein supplementation and exercise training to increase muscle protein synthesis rates in patients with advanced chronic kidney disease

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1. To assess whether the skeletal muscle protein fractional synthesis rate as measured by the deuterated water method is different during a 1-week habitual lifestyle period when compared to a 1-week period with resistance-type exercise and protein…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56016

Source
ToetsingOnline

Brief title
Protein and Exercise Training in chronic kidney disease

Condition

- Other condition
- Nephropathies

Synonym
muscle mass, muscle protein synthesis, Sarcopenia

Health condition

Skeletspier aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Kidney Disease, Exercise, Muscle, Protein

Outcome measures

Primary outcome

The primary outcomes in this study will be daily muscle protein synthesis rates

as measured by the deuterated water method.

Secondary outcome

Secondary study parameters include muscle mitochondrial bioenergetics, muscle

fiber size, leg lean mass, and aerobic capacity muscle mitochondrial

bioenergetics, saliva 2H enrichment, food intake, and physical activity

levels.at baseline.

Study description

Background summary

When patients progress to the final stage of chronic kidney disease (CKD) and require hemodialysis treatment, they typically have lost so much muscle function that they are no longer physically independent. However, due to disease- and hemodialysis-related muscle catabolism, dietary protein and exercise interventions are only capable to attenuate the decline in physical function of patients on hemodialysis treatment. Therefore, lifestyle interventions to increase muscle function should be implemented before hemodialysis is required. However, it is still a matter of debate whether muscle protein synthesis rates of patients with advanced CKD can be increased

with a patient-tailored dietary protein and exercise intervention.

Study objective

1. To assess whether the skeletal muscle protein fractional synthesis rate as measured by the deuterated water method is different during a 1-week habitual lifestyle period when compared to a 1-week period with resistance-type exercise and protein supplementation in patients with advanced CKD.
2. To assess whether the skeletal muscle protein fractional synthesis rate as measured by the deuterated water method differs between patients with advanced CKD and healthy adult controls without CKD, and whether this is affected by a 1-week habitual lifestyle period versus a 1-week period with resistance-type exercise and protein supplementation.

Study design

Randomized cross-over (two treatments) design.

Intervention

Participants will, in a randomized order, be assigned to 1 week of resistance-type exercise training and protein supplementation and 1 week of continuing their habitual lifestyle.

Study burden and risks

The burden and risks involved in participating in this experiment are small. Deuterated water (isotopically labelled water, 2H2O, or *heavy water*) ingestion has been previously used in numerous published studies and is entirely safe and non-toxic when body water enrichments are below approximately 20 mol%. For the current study, body water enrichment will be approximately 1-2 mol%. Muscle biopsies will be obtained under local anesthesia by an experienced physician but may cause some minor discomfort. The discomfort is comparable to muscle soreness or pain comparable to bumping into the corner of a table. During the experimental trial 5 blood samples (100 mL in total) will be obtained through a venipuncture, with the risk of a small local hematoma. Though patients do not directly benefit from participation in the current study, it will provide knowledge about the impact of exercise training and physical activity in patients with CKD, which may help to improve clinical outcomes.

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. In order to be eligible to participate in this study, a patient with CKD must meet all of the following criteria:
• (e)glomerular filtration rate (GFR) <45 ml/min/1.73m2
• Age: 18 - 80 y
• Able to provide written informed consent

2. In order to be eligible to participate in this study, a healthy subject must meet all of the following criteria:
• (e)GFR >60 ml/min//1.73m2 without albuminuria
• Age: 18 - 80 y
• Able to provide written informed consent

Exclusion criteria

• Insulin-dependent diabetes mellitus or two or more oral glucose lowering medications
• Active inflammatory disease / malignancies
• Uncontrolled hypertension (>160/100mm Hg), unstable angina pectoris, or arrhythmia
• Pulmonary disease restricting exercise performance (e.g. COPD)
• A history of neuromuscular problems
• Cognitive Impairment
• Diagnosed GI tract diseases / dysphagia
• Allergies to milk proteins / Lactose intolerance
• Pregnancy
• Hospitalization <1 months prior to study period
• Participation in any structured exercise program
• Any medications known to affect protein metabolism (i.e. corticosteroids or prescription strength acne medications).
• Use of DOAC, vitamin-K-antagonist, or multiple anticoagulants.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-01-2023
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2022
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
Other	Clinicaltrials.gov nummer volgt
CCMO	NL81442.068.22