The effect of protein hydrolysate supplementation to preserve muscle mass during immobilisation and enhance muscle regain during recovery

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24953

Source
Nationaal Trial Register

Brief title
NIR trial

Health condition

healthy, young subjects

Sponsors and support

Primary sponsor: Nuritas
Source(s) of monetary or material Support: Nuritas

Intervention

Outcome measures

Primary outcome

skeletal muscle mass (quadriceps muscle cross sectional area (CSA))

Secondary outcome

maximal leg muscle strength (1RM), whole-leg muscle CSA, type I and II muscle fibre size, muscle protein synthesis rates, and muscle signalling and gene transcription responses

Study description

Background summary

Recovery from illness and/or injury often requires a period of physical inactivity. Short periods of inactivity disrupt muscle protein synthesis and breakdown rates, which lead to a loss of skeletal muscle mass. A loss of skeletal muscle mass has been shown to slow recovery and impact quality of life. It is therefore important to develop strategies that can prevent the loss of skeletal muscle mass during periods of inactivity.With the present study, we will investigate whether dietary supplementation with a protein hydrolysate can attenuate skeletal muscle loss following 7 days of one-legged knee immobilisation and augment the rate of muscle mass re-gain during recovery in young men.

Study objective

We hypothesize that protein hydrolysate supplementation will attenuate the loss in muscle mass during 7 days of immobilisation and will augment the rate of muscle mass re-gain during recovery.

Study design

1 week immobilisation, 2 weeks recovery

Intervention

Subjects will receive a nutritional supplement during immobilisation and recovery. This will be either a protein hydrolysate or a placebo

Contacts

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Eligibility criteria

Inclusion criteria

1) Male
2) Aged 18-35 y
3) BMI 18.5-30.0 kg/m2

Exclusion criteria

1) (Family) history of thrombosis
2) (Family) history of Factor V Leiden, or other known thrombophilia (such as; protein C, protein S, antithrombin deficiency)
3) Lower limb, back or shoulder injuries (which may interfere with the use of crutches)
4) Allergies to milk protein
5) Lactose intolerance
6) Participation in structured resistance exercise program
7) All co-morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g., arthritis, spasticity/rigidity, all neurological disorders and paralysis)
8) Any medications known to (or may) affect protein metabolism (i.e., corticosteroids, non-steroidal anti-inflammatories, or prescription strength acne medications)
9) Diagnosed diabetes
10) Diagnosed metabolic, cardiovascular or intestinal disorders
11) A history of neuromuscular problems
12) Use of anti-coagulants
13) Use of protein and/or fish-oil supplements
14) Participation in a 2H2O study in the previous 6 months.
15) Smoking
16) Any recent hospital admission/ major surgery

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2019
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	03-04-2019
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	NL7645
Other	METC azM/UM : METC18-073

Study results