

The Effect of Creatine Supplementation on Muscle Loss During Immobilisation

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

Summary

ID

NL-OMON40238

Source

ToetsingOnline

Brief title

Creatine and disuse atrophy

Condition

- Muscle disorders

Synonym

Disuse atrophy

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Creatine, Fiber size, Muscle mass

Outcome measures

Primary outcome

quadriceps muscle CSA

Secondary outcome

whole upper leg muscle CSA

muscle fiber type specific CSA

muscle fiber type-specific satellite cell content

1RM muscle strength

Study description

Background summary

Muscle loss can occur for several reasons, such as inactivity because of illness or injury, illnesses themselves or simply old age. A decrease in muscle mass can have a profound impact on quality of life, as it can lead to decreased strength, insulin resistance, lower basal metabolic rate and obesity. One way to induce muscle loss and study its effects is immobilisation. Previous studies have shown that immobilisation of the knee can rapidly induce muscle atrophy. To reduce rehabilitation time following immobilization intervention strategies need to be developed to reduce the loss of muscle during immobilisation. Several nutrients have shown promise regarding the protection of muscle mass in catabolic situations, one of which is creatine. With this study we investigate whether ingesting creatine monohydrate during immobilization will reduce the loss of muscle during a 7 days single leg immobilisation period.

Study objective

The primary aim of this study is to determine the effect of creatine supplementation on muscle mass loss during short-term immobilisation in healthy, young people. In addition, we aim to study the underlying mechanisms of creatine and disuse muscular atrophy.

Study design

The present study will use a randomised, double-blind, placebo-controlled parallel-arm study design with two groups. All volunteers (n=30) will be subjected to 7 days of one legged knee immobilisation by means of a full leg cast, either with (n=15, creatine group) or without (n=15, control group) creatine monohydrate supplementation. The creatine group will be loaded for 5 days prior to immobilisation by providing 20 g of creatine per day. This will ensure that muscular creatine stores are at maximal capacity before the leg is immobilised (13, 26, 27). After the loading phase creatine monohydrate dosage will be reduced to a maintenance dose of 5 g per day, which will be taken during immobilisation and during the recovery week after the immobilisation.

Intervention

One leg will be immobilized at a 30 degree knee joint angle of flexion for 7 days by means of a full leg cast.

In addition, participants will at random be allocated to the creatine group or placebo group. In the week before the 7 day immobilisation period participants in the creatine group will receive 20 g creatine monohydrate per day. During the immobilisation period and post-immobilisation period the participants in the creatine group will receive 5 g of creatine monohydrate per day. In contrast during the 3 week intervention period, participants in the placebo group will receive a placebo.

Study burden and risks

The risks involved in participating in this experiment are minimal.

The incision made for obtaining the muscle biopsy will be performed by an experienced physician and will heal completely. Within our research group we have extensive experience with taking muscle biopsies. During the blood draw there is a small risk of fainting or haematoma. These risks are minimized by using trained and experienced personnel for taking the blood draw and always applying adequate pressure following the blood draw.

The Aviko vacuum-packed and pre-weighed meals are normal food products and have been cleared for human consumption. There are no complications associated with the procedure of a single slice lower limb CT scan.

The immobilization period will lead to loss of muscle mass and strength in the immobilized leg. However, previous studies have shown that this loss in muscle mass and strength returns to pre-immobilized values within weeks after cast removal, without specific training.

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

Male

Aged from 18-35 years

$18.5 < \text{BMI} < 30 \text{ kg/m}^2$

Exclusion criteria

(Family) history of thrombosis

Smoking

Recent surgery < 6 months

Performing regular resistance training more than once per week in the past year

Any back/leg/knee/shoulder complaints which may interfere with the use of crutches

Current systemic use of corticosteroids, growth hormone, testosterone, immunosuppressants or insulin

All co-morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g. arthritis, spasticity/rigidity, all neurological disorders and paralysis)

Use of anti-coagulants

Pre-existing renal disease or those with a potential risk for renal dysfunction (diabetes, hypertension, reduced glomerular filtration rate)

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-09-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	28-08-2013
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
CCMO	NL44547.068.13
Other	nog niet voorhanden

Study results

Date completed:	08-04-2015
Actual enrolment:	30