The effect of leucine and nandrolone decanoate 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-OMON41995

Source
ToetsingOnline

Brief title
nandrolone and leucine during immobilisation

Condition

- Muscle disorders

Synonym
Disuse atrophy, muscle loss

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fiber size, leucine, muscle mass, nandrolone decanoate

Outcome measures

Primary outcome

Quadriceps 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, two of which are nandrolone decanoate (ND) and leucine. With this study we investigate whether ingesting leucine or getting a ND injection during immobilization will reduce the loss of muscle mass and strength during a 7 days sinlge leg immobilisation period.

Study objective

The primary aim of this study is to determine the effect of nandrolone decanoate (ND) injection and leucine supplementation on muscle mass loss during short-term immobilisation in healthy, young people. In addition, we aim to

study the underlying mechanisms of ND and leucine and disuse muscular atrophy.

Study design

The present study will use a randomised, 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 nandrolone decanoate (n=15, ND group) or leucine (n=15, leucine group). The placebo group from a parallel study (METC 13-3-023) will be used as a control group.

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 ad random be allocated to the leucine group or nandrolone decanoate group. Participants in the leucine group get 3x2.5 grams of leucine (every meal) for 1 week (during immobilisation). Participants in the ND group will get 200 mg nandrolone decanoaat at the start of the immobilisation period.

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 hematoma. 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.

Side effects of nandrolone supplementation have been reported, depending on dose and sensitivity: increase libido, hair loss, acne, rash, itch, nausea, muscle soreness, malaise, oedema, increased blood pressure, decreased liver function, bruise or swelling at the injection place, hoarseness, increased prostate or penis, longer and/or sometimes painful erections and disturbance in

forming of sperm cells.

No side effects have been reported for leucine.

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 < BMI < 30 kg/m2

Exclusion criteria

(Family) history of thromboembolic events
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)
Liver disease
Heart failure
Use of insulin or blood sugar decreasing medication or EPO
Migraine
Allergy to nuts or soy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2015
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nandrolone decanoate
Generic name:	Deca-Durabolin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	13-04-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-05-2015
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

ID: 29489
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-000578-37-NL
ClinicalTrials.gov	NCT02376309

Register	ID
CCMO	NL50679.068.15
OMON	NL-OMON29489

Study results

Date completed:	18-05-2016
Actual enrolment:	30