Carnitine status in fit and pre-frail/frail elderly compared to healthy young individuals

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26053

Source
NTR

Brief title
Fitaal

Health condition

Elderly, Frailty, Carnitine, Mitochondrial dysfunction

Ouderen, Kwetsbaarheid, Carnitine, Mitochondriale dysfunctie

Sponsors and support

Primary sponsor: VHL University of Applied Science
Dr. Feike van der Leij
Food & Dairy Applied Research Centre
PO Box 1528, 8901 BV Leeuwarden
E-mail: feike.vanderleij@hvhl.nl
Source(s) of monetary or material Support: VHL University of Applied Science
Food & Dairy Applied Research Centre
PO Box 1528, 8901 BV Leeuwarden
E-mail: feike.vanderleij@hvhl.nl

Medisch Centrum Leeuwarden

PO Box 888, 8901 BR Leeuwarden
Henri Dunantweg 2, 8934 AD Leeuwarden

Wageningen University
Human and Animal Physiology
PO Box 338, 6700 AH Wageningen

Rijksuniversiteit Groningen/Campus Fryslân
PO Box 7560, 8903 JN Leeuwarden
E-mail: campusfryslan@rug.nl

Sigma Tau BV
PO Box 2079, 3500 GB Utrecht

Intervention

Outcome measures

Primary outcome

Intramuscular carnitine levels and carnitine derivatives

Secondary outcome

Carnitine status and its derivatives in PBMCs

Mitochondrial function in muscle tissue and PBMCs

Fat and fat-free mass

Plasma carnitine and its derivatives

Short Physical Performance Battery (SPPB)

400m walk time

Cognitive function

Study description

Background summary

Ageing is associated with increasing physical disabilities and prevalence of frailty, which negatively affects quality of life. In addition, ageing is also associated with a decrease in intramuscular carnitine levels. Simultaneously, intramuscular mitochondrial content and function decline. There are three studies describing the decline in intramuscular carnitine levels during ageing, but none of these studies did measure if
frailty status is associated with the degree of decline in carnitine status and mitochondrial function. In this study we are going to test the hypothesize that declined intramuscular carnitine levels are associated to declined mitochondrial function and, subsequently, to the frailty score.
Therefore the main objective is to compare the intramuscular carnitine status of prefrail/ frail elderly with fit elderly and young individuals. The secondary objectives are; 1) determine if intramuscular carnitine status is associated with carnitine levels in PBMCs; 2) compare lean mass, physical function, muscle function/strength, cognitive function and mitochondrial function in skeletal muscle and PBMCs between fit and pre-frail/frail elderly, by using the healthy young individuals as a reference group.

Study objective

We hypothesize that declined intramuscular carnitine levels are associated to declined mitochondrial function and, subsequently, to the frailty score. We suspect that prefrail/ frail elderly will have the lowest intramuscular carnitine levels and mitochondrial function compared to the fit elderly and healthy young individuals, whereas fit elderly will have higher intramuscular carnitine status and mitochondrial function compared to pre-frail/ frail elderly, but lower compared to healthy young individuals.

Study design

All parameters will be measured within two weeks.

Intervention

A blood sample and muscle biopsy. In addition, participants will perform several physical and cognitive tests and fill in questionnaires.

Contacts

Public
Van Hall Larenstein University of Applied Sciences

M. van der Hoek
Food & Dairy Applied Research Centre - Postbus 1528

Leeuwarden 8901 BV
The Netherlands
+31(0)58 28 46 218
Scientific
Van Hall Larenstein University of Applied Sciences

M. van der Hoek
Food & Dairy Applied Research Centre - Postbus 1528

Leeuwarden 8901 BV
The Netherlands
+31(0)58 28 46 218

Eligibility criteria

Inclusion criteria

Healthy young subjects

- 20-30 years of age

- BMI of 20-25 kg/m2

Healthy fit elderly

- 75 years or older

- Fried score = 0

Pre-frail/frail elderly

- 75 years or older

- Fried score of 1 or more

Exclusion criteria

- Contra-indication for DEXA-scan, e.g. metal splinters

- Contra-indication for muscle biopsy, e.g. use of anticoagulants.

- a significant medical or surgical event or hospitalization within the previous three months

- currently or the last three months treated by a medical specialist

- diagnosed with cardiac failure, COPD or anaemia

- diagnosed dementia and not having access to a daily caregiver and not able to make their own trade-off, which will be assessed at our discretion. The potential subjects have to be able to reproduce what is said;

- diagnosed with cancer or receiving cancer treatment

- not able to understand the Dutch language

- Diagnosed neuromuscular disorders

- taking carnitine supplements

- current participation in other research

- usage of the following medications:

o Systemic corticosteroids

o Fibrates

o Valproic acid

o Emetine

o Zidovudine

Additional exclusion criteria for the young individuals:

- Pregnant and nursing women

- Diabetes Mellitus type I and II

- Limited amount of performing sports, not more than 5 times a week

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-01-2017
Enrollment:	78
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43161
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5943
NTR-old	NTR6124

Register	ID
CCMO	NL58289.081.16
OMON	NL-OMON43161

Study results