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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43161

Source
ToetsingOnline

Brief title
Fitaal

Condition

- Other condition

Synonym
ageing, increasing age

Health condition

veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Medisch Centrum Leeuwarden,Provincie Friesland (Universiteit Groningen/Campus Fryslân);Sigma Tau;Hogeschool Van Hall Larenstein;Wageningen Universiteit;Medisch Centrum Leeuwarden,Sigma Tau B.V.,Wageningen Universiteit

Intervention

Keyword: Carnitine, Elderly, Frailty, Mitochondrial dysfunction

Outcome measures

Primary outcome

The primary study paramater is intramuscular carnitine levels and the

intramuscular carnitine derivatives.

Secondary outcome

The secondary study parameters are:

- carnitine status and its derivates in PBMCs

- mitochondrial function in muscle tissue and PBMCs

- Fat and fat-free mass

- Plasma carnitine and its derivatives

- Short Physical Performance Battery

- 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. We suspect that pre-frail/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 objective

The main objective is to compare the intramuscular carnitine status of pre-frail/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 design

Cross-sectional study

Study burden and risks

In total (including screening), the subjects will visit 3 times the research location. The screening will take about 1 hour for healthy young individuals and 1.5 hours for the elderly. Day 1 of the study will take about 1 hour for young individuals and 2.5 hours for the elderly. Day 2 of the study will take about 1 hours for both the young individuals and the elderly, subsequently a breakfast will be provided to the participants.

One muscle biopsy will be taken during this study. Despite local anaesthesia, there is a small risk of pain during the procedure. In exceptional cases, there can be a minor bleeding afterwards and occurrence of infections. In addition, subjects will undergo a DEXA-scan, whereof regarding the radiation the risks are negligible. Furthermore, there is a small risk of bruising and sore muscles regarding the blood sampling procedures.
Furthermore the subjects will perform a 3-day food diary.

The elderly will also perform a 400-m walk test, cognitive tests, and several balance and physical tests.

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

Healthy young subjects (n <= 26):
* 20 * 30 years of age
* BMI of 20 * 25 kg/m2;Healthy fit elderly subjects (n <= 26):
* * 75 years of age
* Fried score <= 0 ;Pre-frail/frail elderly (n<=26):
* * 75 years of age
* Fried score * 1*;Male/female ratio of the different groups will be matched.

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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	14-12-2016
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	05-12-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	29-06-2017
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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: 26053
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58289.081.16
OMON	NL-OMON26053