Nutritional needs and physical function in community dwelling geriatric outpatients to counteract sarcopenia and ultimately preserve daily function

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To understand the interrelations between muscle related parameters (muscle mass, muscle strength, physical performance), energy expenditure (actual physical activity and basal metabolic rate), and nutritional status (energy intake and protein status...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON42139

Source
ToetsingOnline

Brief title
Nutrition, physical function and sarcopenia in elderly

Condition

- Appetite and general nutritional disorders
- Muscle disorders
- Movement disorders (incl parkinsonism)

Synonym
Sarcopenia; low muscle mass

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Nutricia,Nutricia Research

Intervention

Keyword: Actual physical activity, Energy expenditure, Nutritional status, Sarcopenia

Outcome measures

Primary outcome

The primary study parameter is muscle mass on which the sample size calculation

was made.

- The correlation of muscle mass with the secondary study parameters in

geriatric outpatients.

- The difference in muscle mass between geriatric outpatients and healthy age

matched controls.

Secondary outcome

Muscle-related parameters:

- Muscle strength

- Physical performance

Energy expenditure:

- Basal metabolic rate

- Actual physical activity

Nutritional status:

- Energy intake

- Protein status

Cellular senescence:

- Senescent cells

Study description

Background summary

Sarcopenia, low muscle mass, is one of the undesirable factors leading to physical disability, poor quality of life, loss of independence, and death in older persons. The absence of physical activity diminishes muscle health and a sufficient intake of nutrients, especially protein, has been shown to increase protein synthesis, necessary to regain muscle health.
Very limited data exist in the vulnerable group of elderly referred to geriatric outpatient clinics regarding their muscle related parameters. However, data is lacking on energy expenditure and nutritional status in geriatric outpatients. In geriatric outpatients, the prevalence of undernutrition is significantly higher compared to the general population. Nutritional requirements of the geriatric outpatient population are largely unknown, and therefore nutritional deficiencies are also poorly understood. In clinical practice, optimization of physical and nutritional intervention (*tailored therapy*) to overcome sarcopenia is prevented by lack of knowledge on estimated needs of patients and the interrelation of physical ability and nutritional status. The present study aims to define clusters of patients based on muscle related parameters, energy expenditure and nutritional status in an inception cohort of patients referred to the geriatric outpatient clinic of the Center of Geriatric Medicine Amsterdam (COGA), VU medical center in Amsterdam.

Study objective

To understand the interrelations between muscle related parameters (muscle mass, muscle strength, physical performance), energy expenditure (actual physical activity and basal metabolic rate), and nutritional status (energy intake and protein status) in geriatric outpatients.

Study design

This is an observational, longitudinal study which includes geriatric outpatients with mobility problems and falls referred to the Center of Geriatric Medicine Amsterdam (COGA), VU University Medical Center next to healthy age matched controls.
A total of 220 outpatients and 50 healthy age matched controls will undergo standardized phenotyping on a first visit based on regular care or research setting respectively. On the second visit which takes place one week later, patients will be informed on the results from the first visit and appropriate interventions are prescribed or started. Four months after the first visit,

subjects are subsequently measured again to evaluate results of interventions.

Study burden and risks

Visit 1 includes the following investigations:
- Phenotypic characterization by questionnaires and a Comprehensive Geriatric Assessment (CGA); cognition, depressive symptoms, anthropometric data, physical functioning, cardiovascular functioning, neurological functioning, vision and hearing, blood parameters
- Muscle related parameters assessed by Dual- energy X-ray absorptiometry (DXA) and Bioelectrical Impedance Analysis (BIA)
- Energy expenditure assessed by an accelerometer and indirect calorimetry
- Nutritional status assessed by screening and a food diary.
- Skin biopsy

Visit 2 includes the following investigations:
- Results from the first visit and appropriate interventions

Visit 3 will be a follow up of four months and includes the following investigations:
- Phenotypic characterization; an abbreviated Comprehensive Geriatric Assessment (CGA)
- Muscle related parameters assessed by Bioelectrical Impedance Analysis (BIA)
- Energy expenditure assessed by an accelerometer
- Nutritional status assessed by screening and a food diary

There are only risks associated with the skin biopsy i.e. bleeding of the wound or scar formation.

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

Geriatric outpatients: Elderly referred to the geriatric outpatient clinic of the Center of Geriatric Medicine Amsterdam (COGA), VU University Medical Center Amsterdam.;Healthy age matched controls: Elderly attending social or group activitties, being medically stable, free from major diseases.

Exclusion criteria

Geriatric outpatients: No exclusion criteria will be applied.;Healthy age matched controls: Exclusion criteria from the European MYOAGE study will be applied; dependent living status, the inability to walk a distance of 250 meter, morbidity, immobilization, the use of specific medication, orthopedic surgery , and participation in athletic events.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2015
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL51135.029.14