Effects of Neuromuscular Electrostimulation (NMES) on physical function and skeletal muscle mass in acutely ill hospitalized geriatric patients with sarcopenia admiitted to an acute care geriatric hospital ward

Published: 16-12-2019
Last updated: 10-04-2024

Effects of NMES on physical function and skeletal muscle mass

Ethical review	Approved WMO
Status	Suspended
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON48268

Source
ToetsingOnline

Brief title
NMES in sarcopenic acutely ill hospitalized geriatric patients
NMESSARC

Condition

- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym
sarcopenia; physical function

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Tijd van student en eigen vrije tijd hoofdonderzoeker;verder geen geldstroom

Intervention

Keyword: acute care geriatric ward, frail older adults, Neuromuscular Electrostimulation, sarcopenia

Outcome measures

Primary outcome

Chair stand test timed

Secondary outcome

Knee extension strength measured with a handheld dynamometer (MicroFet-2)

Skeletal muscle mass with bio-impedance analysis (Maltron Bioscan-II)

Study description

Background summary

Aging is associated with loss of skeletal muscle mass and strength, called sarcopenia. Sarcopenia is highly prevalent in hospitalized geriatric patients. It is probably one of the most important causes of functional decline in acutely ill hospitalized geriatric patients. Resistant training is the best therapy to counteract sarcopenia, however geriatric patients are not able to perform this resistance training. Neuromuscular electro stimulation (NMES) could be an alternative way to counteract the negative effects of sarcopenia. In a previous pilot study feasibility was demonstrated.

Study objective

Effects of NMES on physical function and skeletal muscle mass

Study design

Prospective randomised intervention study. Patients will be randomised in two groups: control group (CG) of 30 patients and an intervention group (IG) of 30 patients. The patients in the CG get usual care including physical therapy and patients in the IG get on top neuromuscular electro stimulation (NMES) during 60 minutes a day during working week days. At baseline and at the end of the study physical function is assessed with chair stand test (CST), skeletal muscle strength of the upper legs with a handheld dynamometer (MicroFet-2) and skeletal muscle mass with bio-impedance analysis (Maltron Bioscan-II). A questionnaire is used to assess possible adverse events.

Intervention

The parients in the CG get usual care with daily physical therapy and the patients in the IG get on top on work weekdays during 60 minutes a day NMES (50Hz (10-100 Hz), 400 microsec (100-1000 ms), duty cycle 33% (0-100%)) of the quadriceps muscle on both legs with an amplitude which results in visible muscle contractions. These have to be tolerated by the patients.

Study burden and risks

Serious adverse events are not expected. Temporarily muscle strain, fatigue and skin rash are possible side effects of NMES. We expect an improvement of physical functioning with a better chair rise, improvement of strength of the quadriceps muscles and finally counteract of skeletal muscle mass.

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 patients with sarcopenia according EWGSOP-2 criteria admitted to the acute care geriatric ward
Inclusion and first measurement within the first three days after hospitalization

Exclusion criteria

Inability to walk prior index disease/ hospitalization
Terminal condition eg due to metastatic cancer
Inability to walk due to pain of parese
ICD
No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	29-11-2019
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	Neuromuscular Electrostimulation (En-Stim 4 Enraf Nonius)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-12-2019
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL71911.096.19