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

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Neuromuscular electro stimulation (NMES) has additional effects on top of tailor made exercise training to counteract the negative effects of sarcopenia .

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23883

Bron
Nationaal Trial Register

Verkorte titel
NMESSARC

Aandoening

Sarcopenia should be present. Patients are however admitted to the geriatric ward because of multiple problems mostly acute

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To study the effects of NMES on top of exercise training on physical function and skeletal muscle mass in acutely ill sarcopenic hospitalized geriatric patients. Effects will be measured with the timed Chair Stand Test (t-CST), knee extension force (KEF) assessed with a handheld dynamometer (MicroFet-2) and skeletal muscle mass of the upper leg (ul-SMM) with multifrequency bio-impedance analysis (mf-BIA). The difference in percentage of patients with changes on these parameters (t-CST, KEF and ul-SMM) in the IG compared to the patients in the CG.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 electrostimulation (NMES) could be an alternative way to counteract the negative effects of sarcopenia. In previous studies effectivity and feasibility was demonstrated in different populations. However no studies with NMES are performed in the acutely ill hospitalized geriatric patient with sarcopenia.
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 electrostimulation (NMES) during 60 minutes a day during 5 days on consecutively working week days. At baseline and at the end of the study physical function will be assessed with timed chair stand test (t-CST), knee extension strength (KES) of the upper legs with a handheld dynamometer (MicroFet-2) and skeletal muscle mass of the upper leg (ul- SMM) with bio-impedance analysis (Maltron Bioscan-II). A questionnaire will be used to assess possible adverse events.
Study population: Acutely ill geriatric patients with sarcopenia admitted to the acute care geriatric ward of Zuyderland Medical Centre.
Intervention (if applicable): The patients in the CG will get usual care with daily physical therapy and the patients in the IG will get NMES (50Hz (10-100 Hz), 400 microsec (100-1000 ms), duty cycle 33% (0-100%)) during 60 minutes a day of the quadriceps muscle on both legs during 5 days. The amplitude will be set individually and have to result in visible muscle contractions and must be tolerated by the patients.

Main study parameters/endpoints: Primary endpoint is the difference in percentage of patients in the IG compared to the patients in the CG with changes on the t-CST. The secondary endpoints are the differences in percentages of patients in the IG compared to the patients in the CG with changes in KES and changes in ul-SMM.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 loss of skeletal muscle mass.

Doel van het onderzoek

Neuromuscular electro stimulation (NMES) has additional effects on top of tailor made exercise training to counteract the negative effects of sarcopenia .

Onderzoeksopzet

Baseline and after 5 days NMES on top of tailor made exercise training in the IG or in CG after 5 days tailor made exercise training

Onderzoeksproduct en/of interventie

The patients in the control group (CG) will get usual care with daily physical therapy and the patients in the intervention group (IG) will get on top NMES during 5 days on working weekdays during 60 minutes a day. The NMES basic settings are: 50Hz (10-100 Hz), 400 microsec (100-1000 ms) with a duty cycle of 33% (0-100%) based on the earlier studies.5,6,14 NMES of the quadriceps muscle on both legs will be done simultaneously. The amplitude will be tapered by the researcher in agreement with the individual patient and have to result in visible muscle contractions. These muscle contractions have to be tolerated by the patients and the maximum of the amplitude is there for individualized

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a patient must meet all of the following criteria: aged 70 years and older, being frail according the Groningen Frailty Indicator (GFI score >3) and they should be sarcopenic according the European Working Group On Sarcopenia-2 criteria (EWGSOP-2) based on handgrip strength (men < 27kg and women < 16kg)), appendicular skeletal muscle mass (men < 7.0 kg/l2 and women < 7.0 kg/l2) and physical function below cut-off values (Short Physical Performance Battery <9). In a study done by Sipers et all in this population 92% of the men and 67% of the women were sarcopenic.3 Inclusion and first measurement should be done within the first three days after hospitalization.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential patient will be excluded from participation in this study if he/she meets any of the following criteria: Inability to walk prior index disease or problem before hospitalization. If a patient has a terminal condition e.g. due to metastatic cancer with a limited survival time (less than 3 month). Inability to walk due to pain or palsy during hospital stay. If a patient is not instruct able. If a patient has an implantable cardioverter defibrillator (ICD) or no informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-03-2020
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Not available at this moment

Ethische beoordeling

Positief advies

Datum:	11-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8454
Ander register	METC Zuyderland-Zuyd : METCZ20190134

Resultaten

Samenvatting resultaten
Planned after the study trail