Myokines and cognitive aging in people with spinal cord injury: a single case experimental design study

Published: 09-10-2023
Last updated: 30-01-2025

To assess to what extent a 12 weeks intervention consisting of Neuromuscular electrical stimulation (NMES) to the quadriceps muscles may change cognitive function and blood levels of the biomarker Brain-derived neurotrophic factor (BDNF) in persons...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON56022

Source
ToetsingOnline

Brief title
myokines and cognitive aging in SCI

Condition

- Spinal cord and nerve root disorders

Synonym
myelopathy, spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderwijs Limburg (SWOL)

Intervention

Keyword: cognition, myokines, neuromuscular electrical stimulation, spinal cord injury

Outcome measures

Primary outcome

Response time and %accuracy on an executive function task

Secondary outcome

A cognitive test battery and blood collection for the assessment of

Brain-derived neurotrophic factor (BDNF) levels. Other measured variables are

important for taking into account potential moderating effects.

Study description

Background summary

Individuals with spinal cord injury (SCI) suffer from accelerated cognitive aging. Brain-derived neurotrophic factor (BDNF) is a facilitator of neuroplastic processes, which is released from contracting muscles. In healthy older adults it is the suggested mechanism of exercise-induced cognitive improvements. Neuromuscular electrical stimulation (NMES) has the potential to induce BDNF and induce cognitive improvements in people with SCI.

Study objective

To assess to what extent a 12 weeks intervention consisting of Neuromuscular electrical stimulation (NMES) to the quadriceps muscles may change cognitive function and blood levels of the biomarker Brain-derived neurotrophic factor (BDNF) in persons with spinal cord injury.

Study design

Single center, single case experimental design with a single-armed prospective study design

Intervention

Neuromuscular electrical stimulation

Study burden and risks

Every participant will be asked to visit the research center 5 times. The intervention consists of 12 weeks of 3x30min per week of neuromuscular electrical stimulation and cognitive tests 3x30sec per week for 18-21 weeks. The electrical stimulation is being used as intended, and has therefore a low risk of injury.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 hx
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 hx
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Persons with spinal cord injury
-Completeness of injury: AIS A, B or C
-Level of injury: L2 or higher
-At least 18 years old
-Chronic stage (> 1 year) since injury
-No previous surgery to the quadriceps muscles
-Able to use apps on smartphone (i.e. participants should have their own smartphone and should not have disabilities that impair them to operate it independently)
-Able to follow the instructions of placing the surface electrodes of the NMES device correctly or to have someone else put the electrodes for them
-Dutch as a native language

Exclusion criteria

-Malignant processes, or history of undergoing chemotherapy, or history of radiotherapy to the head
-No visible or palpable contraction of the quadriceps muscle upon electrical stimulation
-Intolerance to electrical stimulation of the quadriceps muscle
-Recent or current participation in an electrical stimulation-induced exercise or therapy program in which regular electrical stimulation was given (up to 6 months prior to study inclusion)
-Known neurodegenerative disorder, such as Alzheimer*s disease or Parkinson*s disease
-Known psychiatric disorder, such as major depressive disorder or bipolar disorder
-Current pressure ulcer
-History of severe autonomic dysreflexia
-Metal implants in the electrical stimulation area
-Intrathecal baclofen (ITB) device
-Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-01-2024
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
ClinicalTrials.gov	NCT05822297
CCMO	NL84287.015.23