Optimal neurophysiological parameters in neuromuscular electrical stimulation in the treatment of dysphagia in multiple sclerosis - a pilot study

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Primary Objective: To develop a protocol for NMES for dysphagia to determine optimal electrode placement and stimulation parameters in MS patients.Secondary Objective: To determine variability in location, morphology, and type of motor dysfunctions...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON47927

Source
ToetsingOnline

Brief title
NMES for dysphagia in MS

Condition

- Demyelinating disorders

Synonym
dysphagia, Swallowing disorders

Research involving
Human

Sponsors and support

Primary sponsor: Nieuw Unicum

Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: dysphagia, multiple sclerosis, neuromuscular electrical stimulation

Outcome measures

Primary outcome

A protocol to determine optimal electrode placement and neuromuscular electrical stimulation parameters for NMES for dysphagia in individual MS patients.

Secondary outcome

The variability in location and type of motor dysfunctions of hyoid muscles in patients with MS visualized with ultrasonography.

Study description

Background summary

The reported incidence of dysphagia in multiple sclerosis (MS) varies between 33% and 90% and is higher in more disabled patients. Dysphagia is associated with an increased risk of aspiration pneumonia, increase in health-care cost and increase in mortality and a decrease of quality of life (QOL). Patients with oropharyngeal swallowing problems are commonly referred to a speech-therapist for further assessment and treatment.
Limited evidence is available for treatment of dysphagia in MS. A significant decrease of dysphagia in MS after treatment with neuromuscular electrical stimulation (NMES) was found, but in other studies the results of the effect of NMES on dysphagia were inconsistent. Therefore, the need for research into the optimal parameters for the application of NMES is clear.

Study objective

Primary Objective: To develop a protocol for NMES for dysphagia to determine optimal electrode placement and stimulation parameters in MS patients.
Secondary Objective: To determine variability in location, morphology, and type of motor dysfunctions of hyoid muscles visualized with ultrasonography in MS

patients.

With this pilot study we will be able to develop a protocol for the application of NMES for dysphagia in order to find individualized optimal electrode placement and stimulation characteristics based on location, morphology and type of motor dysfunctions that are present. In a follow up study the effect of the NMES in the treatment of dysphagia in MS patients will be tested in a randomized controlled trial following the developed protocol.

Study design

An explorative fundamental study based on a convenience sample. The DYMUS will be used to screen patients for dysphagia. Fiberoptic endoscopy (FEES) will be assessed by a speech and language therapist to determine the severity of the dysphagia. Within two weeks a proficient physiotherapist will use ultrasonography to determine the location and assess the morphology of the hyoid muscles. Immediately thereafter an experienced speech therapist will use electrical stimulation to stimulate the hyoid muscles. Simultaneously, ultrasonography will be used to guide optimal electrode placement and stimulation characteristics. Displacement of the hyoid bone will be measured and abnormalities in muscle contractions will be noted. For every electrode position, optimal stimulation parameters (amplitude (*A), pulse duration and frequency (Hz)) will be determined by noting the thresholds for muscle contraction. The comfort of the patients during stimulation will be taken into account in finding optimal stimulation parameters.

Intervention

The patients receive neuromuscular electrical stimulation during a test setting.

Study burden and risks

Burden:
All examinations take place within clinical staff rooms and departments of Nieuw Unicum.

The participants will have 2 or 3 contact moments to complete the entire examination. The total duration of the study is approximately 4 weeks.
Time investment: 3 sessions of 15 + 60 + 10 = 85 minutes in total.

Risks:
FEES
Despite of the various advantages of FEES, this diagnostic procedure is not without risks. The most probable consequences are discomfort, gagging and/or vomiting, vasovagal syncope, epistaxis, mucosal perforation and laryngospasm.

Those consequences do not appear frequently. Langmore, Pelletier & Nelson (1995) reported 2 incidences of laryngospasmen (0.03%), 4 vasovagal episodes (0.06%) and 20 incidences of epistaxis (0.3%) in 6000 FEES examinations.

Ultrasonography
An ultrasound is a completely painless and harmless procedure.

NMES
NMES is a specialized non-invasive form of electrical stimulation therapy designed to treat dysphagia. The electrical current may start off as a slight tingling sensation and build to a pulling sensation. For NMES no associated risks are known at this time (NICE, 2014). Side effects include redness and irritation to the skin, which typically clears with topical moisturizer in 24 to 48 hours. Up to one day after NMES, myalgia of the hyoid muscles can be experienced.

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

(1) at least 18 years of age
(2) a confirmed diagnosis of MS
(3) a diagnosis of dysphagia determined by FEES characterized by incomplete hyoid movement.

Exclusion criteria

(1) individuals with other neurological disorders
(2) individuals with obstruction in nasal passage (FEES will not be possible)
(3) individuals with significant cognitive deficits who cannot follow instructions during FEES or are not able to provide feedback on sensing stimulation or pain in their head and neck and
(4) individuals who are medically not stable enough to be able to participate in FEES (e.g. pneumonia or fever)
(5) radiotherapy in head/neck area or oncology of head/neck area
(6) in case of heart problems, metal implants in head/neck area, inflamed skin, implanted stimulators or electronic devices participation should be evaluated by a medical doctor.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Electrotherapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-07-2018
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

ID: 29473
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62007.029.17
OMON	NL-OMON29473