Electrode usability during a multiday abdominal NMES program

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-To determine which type of NMES electrodes is most suitable for multiday (5 days) use. The main objective is to explore the effect of time and electrode type on skin condition during multiday use of the same electrodes in healthy subjects.

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

Summary

ID

NL-OMON45458

Source
ToetsingOnline

Brief title
VU-UT-01

Condition

- Muscle disorders
- Respiratory disorders NEC

Synonym
N/A

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: electrode type, electrode-skin contact, healthy subjects, multiday neuromuscular electrical stimulation

Outcome measures

Primary outcome

Changes in physiological properties of the electrode-skin contact, during

multiday NMES sessions.

Primary endpoint:

- Condition of the skin, measured in categories of dermal response.

Secondary outcome

Secondary parameters:

- Series resistance (electrode + skin resistance)

- Electrode adhesion

- The difference in electrode resistance and capacitance before and after 5

days of use

- Change in stimulus effect during multiday use of the same electrodes,

measured as:

- Maximal comfortable stimulation intensity

- Sensitivity to stimulation

- Abdominal muscle contraction, measured with ultrasound

Study description

Background summary

Development of respiratory muscle weakness is a major clinical problem in

patients that are mechanically ventilated at the intensive care unit (ICU). Respiratory muscle weakness occurs in these patients primarily because mechanical ventilation can partially or completely unload the respiratory muscles, which results in the development of disuse atrophy. This is associated with adverse outcomes, including prolonged duration of mechanical ventilation and mortality. While considerable research within this context is focused on the diaphragm (main inspiratory muscle), the effects of critical illness on expiratory muscle function has not been studied. The main expiratory muscles are the abdominal wall muscles, which are important for airway clearance and coughing. Weakness of these muscles lead to poor cough function and (re)hospitalization for respiratory complications.

We are currently conducting a clinical study that is focused on the prevention of expiratory muscle weakness (NL57058.091.16, CMO 2016-2366 file at CMO Arnhem-Nijmegen, multicenter study with VUmc). Because most patients are sedated, they cannot participate in active physiotherapy. For this reason neuromuscular electrical stimulation (NMES) of the expiratory abdominal wall muscles is applied two times a day. We expect that cough function can be maintained and that patients will wean earlier from the ventilator.

NMES uses surface electrodes to apply stimulation to muscles. For practical and clinical reasons, we are replacing the electrodes every five days in our ongoing clinical study (NL57058.091.16, CMO 2016-2366 file at CMO Arnhem-Nijmegen), as renewing the electrodes on a daily basis is time-consuming, more expensive and might negatively affect skin structure and function. Prolonged use of the same electrodes, however, might affect the condition of the electrode-skin contact and such NMES effectiveness. In general, one aspect of NMES therapy that is not well described in the literature is whether multiday use of NMES electrodes influences the effectiveness of NMES therapy.
In the current study we aim to compare three types of electrodes to determine which type is most suitable for multiday use. This will be evaluated in healthy subjects so that measurements do not interfere with our study in ICU patients. Results of the current study will be used to determine which type of electrode is most suitable to use in future clinical studies or implementation of NMES at the ICU.

Study objective

-To determine which type of NMES electrodes is most suitable for multiday (5 days) use. The main objective is to explore the effect of time and electrode type on skin condition during multiday use of the same electrodes in healthy subjects.

Study design

Explorative pilot study

Intervention

The expiratory abdominal wall muscles will be stimulated for two times a day for a period of five consecutive days. This is done through similar protocols that are used in the study in ICU-patients. The current study does not aim to evaluate the effect of muscle stimulation on muscle mass and properties, but on the usability/efficiency of three types of surface electrodes.

Study burden and risks

We believe that there are minimal risks associated with participation. The study will be performed with the goal to help in decision-making regarding multiday use of electrodes for a future clinical study / implementation. Because this study is performed in healthy subjects within the guidelines for use of the device and electrodes, we expect minimum risks for participating in this study. The subject decides the stimulation intensity so that stimulation is applied with an intensity that is comforatble for the subject. This intensity can be changed during the stimulation sessions based on the needs of the subject; both an increase (due to habituation) or decrease in intensity is possible. If skin irritation occurs during stimulation sessions, stimulation sessions will be stopped immediately.
There are several aspects of this study that could be regarded as inconveniences to study participants. Subjects need to wear electrodes on their skin for 5 consecutive days; during this period, subjects are asked to avoid extensive transpiration, such as induced by strenuous exercise or sun bathing, since this could possibly affect electrode quality. However, subjects are aware of these inconveniences before they decide to participate in the study. There will be small benefits for the participants, as it is known that muscle stimulation can be beneficial in terms of improving muscle strength.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117

Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Informed consent
- Age > 18 year
- Healthy

Exclusion criteria

- Recent abdominal surgery (< 1 month)
- Pre-existent neuromuscular problems
- Cardiac pacemaker
- BMI > 35 kg/m2
- Dermatological disease that effects the abdominal wall
- Pregnancy, breast feeding

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):	15-05-2017
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Electrical muscle stimulator (FDA-certified)
Registration:	No

Ethics review

Approved WMO

Date:	10-04-2017
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	NL60597.029.17