The effect of a single session of whole-body neuromuscular electrical stimulation (NMES), with or without subsequent intake of a protein bolus, on whole-body protein turnover in sedated intensive care unit (ICU) patients

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To examine the effect of a single session of whole-body NMES, with or without subsequent protein intake, on whole-body protein turnover

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON57151

Source
ToetsingOnline

Brief title
Short NMES and protein intake on WB protein turnover in ICU (SPICE I)

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym
insulin resistance, Muscle loss

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: NWO Mozaïek 2.0 aan Drs. Lauryn Domingos

Intervention

Keyword: Intensive Care Unit, Muscle Metabolism, Neuromuscular electrcial stimualtion (NMES), Protein Intake

Outcome measures

Primary outcome

Whole-body protein net balance (WPNB)

Secondary outcome

Whole body protein synthesis, breakdown, and oxidation. Forearm muscle glucose

uptake (i.e. a direct measure of muscle insulin sensitivity).

Study description

Background summary

Intensive care unit (ICU) stay is accompanied by muscle wasting (i.e. the loss of muscle proteins) and ICU-acquired weakness (ICU-AW), which lead to increased time of mechanical ventilation, morbidity, negative post-ICU consequences and an overall decreased quality of life (QoL). The building blocks of our muscles, called amino acids, are primarily acquired through dietary intake. A fundamental cause for ICU-induced muscle wasting is an impaired response to the anabolic properties of dietary protein. Neuromuscular electrical stimulation (NMES) could stimulate muscle amino acid metabolism and alleviate some of these negative consequences by reintroducing (involuntary) muscle contractions via small electric currents. Previous research has shown that NMES of the quadriceps muscle alleviated muscle wasting in sedated patients. At present, the effects of a whole-body NMES approach in combination with timed protein intake on amino acid metabolism in ICU patients remain unknown.

Study objective

To examine the effect of a single session of whole-body NMES, with or without subsequent protein intake, on whole-body protein turnover

Study design

Randomised, placebo-controlled design with three parallel groups

Intervention

A single test day during which participants will either receive sham-NMES followed by standard enteral nutrition (CON), whole-body NMES stimulation followed by standard enteral nutrition (WB-NMES), or whole-body NMES followed by a bolus of 20g protein (WB-NMES+PRO). Continuous intravenous infusion of labelled amino acids will be combined with repeated blood samples. Doppler ultrasound measurements will be performed before blood sampling to determine forearm amino acid and glucose balances.

Study burden and risks

We will use the arterial and central venous lines that have already been inserted for blood drawing. A cannula will be placed in the elbow crease to collect blood. If not in situ, another cannula will be placed for stable isotope infusion. Insertion of the catheters in a vein is comparable to a routine blood draw, and the only risk is a small local hematoma. The standard nutrition provided is part of the routine care in the ICU, so it poses no extra risks. Short fasting periods are common in this population and pose no risks. NMES has been applied to critically ill patients by ourselves and others, and it has been proven safe when applied by trained staff. The protein bolus is commonly used in current practice in ZGV. The labelled, non-radioactive amino acid tracers that will be infused intravenously are produced under sterile conditions according to GMP standards and routinely used in human skeletal muscle metabolism research.

Contacts

Public
Wageningen Universiteit

De Elst 1
Wageningen 6708 WD
NL
Scientific

Wageningen Universiteit

De Elst 1
Wageningen 6708 WD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Aged >=18 years
• Expected to need mechanical ventilation for at least 48 hours, judged by physician
• Expected to reach a Richmond Agitation-Sedation Scale (RASS) score of -4 or -5 (complete
sedation), judged by physician
• Informed consent obtained from the next-of-kin
• Able to or are receiving enteral nutrition
• Have an arterial and a venous line

Exclusion criteria

• Spinal cord injury
• Previous surgery/local wounds that prohibit NMES
• Conditions that prohibit NMES (such as open wounds)
• Chronic neuromuscular disorders
• Acute Kidney Injury (AKI) II and III
• Undergoing continuous veno-venous hemofiltration (CVVH)
• Rhabdomyolysis (based on plasma creatine kinase levels)
• Neuromuscular blocking agents
• In the caloric restriction period of refeeding syndrome
• In prone position

• Burn wounds
• ICD/pacemaker
• Pregnant
• Deemed not suitable to participate based upon the judgement of the treating intensivist

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	17-10-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL87298.028.24