Feasibility of skeletal muscle biopsy and near-infrared spectrometry in post-ICU patients: the Powerhouse feasibility study

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To investigate the feasibility of Bergström needle biopsies of the vastus lateralis muscle, and NIRS measurements of the gastrocnemius muscle in post-ICU patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56670

Source
ToetsingOnline

Brief title
Powerhouse Feasibility study

Condition

- Other condition
- Vitamin related disorders

Synonym
Post-Intensive Care Syndrome, Recovery issues after Intensive Care admission

Health condition

Post-Intensive Care Syndroom

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei
Source(s) of monetary or material Support: Danone Nutricia Research,Nutricia

Intervention

Keyword: Intensive Care Unit, Mitochondria, Near-infrared spectrometrie, Post Intensive Care Syndrome

Outcome measures

Primary outcome

The primary study endpoint is the feasibility of 3 mm Bergstro*m biopsies of the vastus lateralis muscle and NIRS measurements of the gastrocnemius muscle in post-ICU patients. In order to determine this the following main parameters will be collected: - The acceptability for participation in the study, which is expressed as the number of eligible patients approached for participation in the study and the proportion of included patients as collected in a pre-screenings log. - Results from the questionnaire following NIRS measurements and the muscle biopsy, including pain rate, burden and willingness to undergo a secondary NIRS and/or muscle biopsy at hospital discharge. - The practical feasibility of NIRS measurement and biopsies of skeletal muscles in the post-ICU patient. - Reliability of NIRS assessment of mitochondrial capacity of the GA muscle in post-ICU patients as shown by reliable post-exercise mVO2 recovery curves (R2 > 0.90 by mono-exponential curve fitting).

Secondary outcome

The secondary endpoints include:

- Amount of muscle tissue retrieved from a single 3 mm Bergström vastus lateralis muscle biopsy.

- Muscle fibre type distribution and size of the vastus lateralis muscle sample of post ICU patients.

- (Serious) adverse effects (SAE) following muscle biopsy and NIRS of skeletal muscles.

- Quality of the muscle biopsy, as determined by a successful whole genome transcriptome analyses (RNA sequencing)

- Re-oxygenation rate measured using NIRS after the release of the occlusion

- Variation in NIRS-derived parameters between included subjects

Study description

Background summary

Muscle weakness following critical illness is mainly the result of decreased skeletal muscle mitochondrial function and capacity. Decreased physical condition after admission to the intensive care unit (ICU) is considered part of the post-intensive care syndrome (PICS). It is associated with morbidity and mortality in post-ICU patients. Specific nutritional components have the potential to recover muscle mitochondrial function and, thereby, the physical function of these patients, but it requires a randomized controlled trial to investigate this. The gold standard of evaluating skeletal muscle mitochondrial function is obtained by the respiratory function of muscle cells retrieved by muscle biopsy, preferably by the modified Bergström biopsy technique. However, patients recovering from ICU admission may be reluctant to undergo this invasive method as they are still rehabilitating from critical illness. An alternative method of evaluating mitochondrial functioning is muscle near-infrared spectrometry (NIRS). NIRS measures the recovery of muscle oxygen consumption (mVO2) post-exercise as a parameter for mitochondrial capacity. Before conducting a randomized controlled trial to investigate the effect of nutritional components on skeletal muscle mitochondrial functioning, we will perform a prospective pilot study to evaluate the feasibility and acceptability of muscle biopsy and NIRS in patients who will be discharged from the ICU.

Study objective

To investigate the feasibility of Bergström needle biopsies of the vastus lateralis muscle, and NIRS measurements of the gastrocnemius muscle in post-ICU patients.

Study design

Cross-sectional, single-centre pilot study.

Study burden and risks

After inclusion, NIRS with transient arterial occlusions of the gastrocnemius muscle will be performed once. Subjects may experience some discomfort from the transient occlusions. However, there is no risk of complications. Consequently, a biopsy of the vastus lateralis will be performed once using a 3 mm modified Bergström needle. An experienced physician will take muscle biopsies under local anaesthesia but the procedure carries a small local hematoma risk and may cause minor discomfort up to 24 h after the procedure. One questionnaire will be taken directly after the NIRS and biopsy, but no follow-up is needed. A team of experienced specialists will carry out the procedures to minimize the risk of complications. There is no direct benefit for the participants except for their contribution to scientific knowledge. This pilot study will provide crucial information to set up a randomized controlled trial, which will provide new insights into the effects of micronutrients on restoring skeletal muscle mitochondrial function of post-ICU patients, for which evidence-based therapies are currently lacking.

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) >=18 years of age 2) Medical research council (MRC) sum score of at least 24 and less than 48 3) Serum haemoglobin of at least 5.0 mmol/L 4) BMI < 30 kg/m2 5) Admitted to an intensive care unit for at least 72 hours 6) exptected to be discharged from the ICU within 48 hours 7) Written informed consent

Exclusion criteria

1) Known mitochondrial disease
2) Pre-existent muscle disease
3) Diabetes Mellitus
4) Life expectancy less than 6 months
5) Visibly high melanin content in the skin
6) Subcutaneous fat layer > 3cm covering the GA muscle (measured by ultrasound)
7) Coagulopathy (i.e. platelet count; < 50 x10 9 cells/ml, INR > 2.0 or recent treatment with therapeutic dosage of low molecular weight heparin)
8) Recent lower extremity surgery
9) Delirium (defined as a delirium observation screening scale (DOS) of at least three)
10) Deemed incompetent to provide well-considered informed consent by the treating physician

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2023
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO Date:	27-03-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-04-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL84638.081.23