Early mobilization in the Intensive and Medium care unit by the use of mobile monitoring: a single center randomized trial

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The aim of the study is to investigate whether the use of telemetry monitoring leads to the promotion of early mobilization, by an improvement in mobilization and strength measurements, in rehabilitating ICU/MCU patients. Secondary goal is whether...

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Other condition
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON53218

Source
ToetsingOnline

Brief title
EARLY-MOB trial

Condition

- Other condition

Synonym
early mobilization ICU rehabilitation stage

Research involving
Human

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis

Source(s) of monetary or material Support: St. Antonius onderzoeksfonds

Intervention

- Other intervention

Keyword: critically ill patient, mobilization, Psychological monitoring, Telemetry

Explanation

N.a.

Outcome measures

Primary outcome

Primary Goal:
- Early mobilization measured by DEMMI score (within 24-48 hours after
inclusion of the study and then twice a week by physiotherapist)
- Muscle strength measured by MRC-SUM (within 24-48 hours after inclusion of
the study and then twice a week by physiotherapist)

Secondary outcome

- Reducing anxiety and depression measured by HADS score at the time of
inclusion of the study and in the first hours after discharge to the ward.
- Feeling more safe measured by one question at the time of inclusion of the
study and in the first hours after discharge to the ward.

Study description

Background summary

Increasingly, Intensive and Medium Care unit (ICU/MCU) patients stay longer in the ICU/MCU for several reasons. These patients still have an ICU/MCU indication, but vital signs no longer need to be intensively monitored. These patients are no longer critically ill, but are in a rehabilitation stage. They still receive continuous monitoring until discharge to the ward. Early mobilization is one of the most important interventions in this rehabilitation stage but bedside monitoring limits patient's freedom and mobilization possibilities.

Study objective

The aim of the study is to investigate whether the use of telemetry monitoring leads to the promotion of early mobilization, by an improvement in mobilization and strength measurements, in rehabilitating ICU/MCU patients.
Secondary goal is whether this telemetry monitoring reduces stress and anxiety around discharge to the ward (without continuous monitoring vital signs).

Study design

Randomized control trial with an unblinded intervention and control group.

Intervention

The intervention means monitoring with telemetry until discharge to the ward.
The control group maintains conventional bedside monitoring until discharge to the ward.

Study burden and risks

The rehabilitating ICU/MCU patient receives more appropriate vital signs monitoring care, which may have a positive effect on early mobilization and may also reduce stress and anxiety and increase the sense of security around transfer to the ward without continuous monitoring vital signs.
A pilot study at the MCU in the St. Antonius hospital (2022) has already shown that the introduction of telemetry monitoring is safe and accepted by healthcare professionals on the MCU.

Contacts

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Trial sites

Trial sites in the Netherlands

St. Antonius Ziekenhuis
Target size: 82

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• >=18 years
• Minimum ICU/MCU stay 5 days
• No expected discharge to the ward without continuous monitoring vital signs within 48 hours
• Meets pre-defined criteria:
o Hemodynamic stability
o No use of inotropes/vasopressors
o Not external pacemaker dependent
o No significant cardiac arrhythmia or intervention in the last 48 hours
• No arterial pressure catheter/line
• Signed informed consent

Exclusion criteria

- CVA during hospital admission, with limited mobility (hemiparesis)
- Paraplegia due to myelum ischemia after aortic surgery
- Guillain-Barre
- Prescribed bed rest (e.g. type B dissection)
- No signed informed consent
- Not instructable or limited mobility
- Patient has already been included in the study during hospital admission

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	29-10-2023
Enrollment:	82
Duration:	1 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	13-07-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	02-04-2025
Application type:	Amendment
Review commission:	MEC-U

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	NL84541.100.23
Research portal	NL-006139