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Early proprioceptive stimulations in mechanically ventilated critically ill patients

Submission date	**Recruitment status**	[_] Prospectively registered
05/03/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/03/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/03/2023	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

After a stay in the intensive care unit (ICU), patients often have conditions unlinked to their initial reason for hospitalization. These conditions affect the physical, psychological, and cognitive aspects of patients' lives. They are grouped under the term post-intensive care syndrome (PICS). Recognition of this syndrome has triggered a paradigm shift in ICU practices in the past few years. One aspect that has been discussed a lot is prolonged bed rest. Helping patients be mobile or early mobilization in the ICU has then been studied, and its benefits have been proven. However, the timing, type, and intensity of the intervention still need to be defined. The present study focuses on a treatment called functional proprioceptive stimulations (FPS). This technique uses tendon vibrations to reproduce the signatures of the movements such as those used in walking (flexion/extension). It can be applied to unconscious or sedated patients, allowing it to be implemented early during the ICU stay. Some studies have already demonstrated the benefits of proprioceptive vibrations. However, these benefits have only been studied at the chronic stage of neurological diseases. The team hypothesize that early FPS might lessen the harmful effects of an ICU stay. In this study, better functional status and less muscle wasting are expected at discharge from the ICU. This study will help clarify the value of such an early and intensive intervention in mechanically ventilated critically ill patients.

Who can participate?

Patients hospitalized in the ICU of a single center

What does the study involve?

To test the hypothesis, a randomized controlled trial is being conducted on patients in ICU who have been mechanically ventilated for at least 48 hours. These patients are stratified into two groups according to the presence or absence of a central nervous system lesion. Within five days after admission, patients are included and either receive FPS added to standard mobilization or standard mobilization alone. FPS are delivered to the joints of the lower limbs four times a week during the ICU stay. The primary outcome measure assesses functional status at discharge from the ICU. Secondary outcomes include muscle strength, muscle wasting, cognitive impairment, and spasticity when appropriate. A smaller incidence of ICU-acquired weakness is expected in the experimental group than in the control group.

What are the possible benefits and risks of participating?
The expected benefits are a limitation of the harmful effects of prolonged bed rest and immobilization, especially on the functional status. The risks are minimal: apart from possible transient skin reddening, no side effect related to using the FPS is expected in this study.

Where is the study run from?
Hôpital Bicêtre (France)

When is the study starting and how long is it expected to run for?
May 2022 to May 2024

Who is funding the study?
1. The equipment used in this study belongs to the Bicêtre hospital. And one of the investigators is supported by a PhD grant (CIFRE fellowship N°2020/1605) co-funded by the National Association for Research in Technology (Association Nationale de la Recherche Technique; ANRT) and Techno Concept (Manosque, France).
2. Association MAPAR (Mise Au Point Anesthésie Réanimation) (France)
3. Assistance Publique - Hôpitaux de Paris/Public Assistance Hospital of Paris (France)

Who is the main contact?
Bernard Vigue, bernard.vigue@aphp.fr (France)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RCB 2022-A01277-36

Study information

Scientific Title
Assessment of the effects of early proprioceptive stimulations on the functional status of mechanically ventilated critically ill patients: a randomized controlled trial

Acronym
REA-MOUV

Study objectives
Early functional proprioceptive stimulations (FPS) mitigate the harmful effect of an ICU stay.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 19/12/2022, Committee for the protection of individuals West 5 (Comité de protection des personnes Ouest V, CHU Pontchaillou - 9, Avenue de la Bataille Flandres Dunkerque Mai 1940, 35033 Rennes Cedex 09, France; +33 (0)2 99 28 25 56; cpp.ouestv@chu-rennes.fr), ref: 22.03429.000144

Study design
Single-center interventional randomized controlled study (examiner blinded)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Early rehabilitation of critically ill patients

Interventions
The control group receives standard treatment usually provided in the ICU.

The intervention group receives standard treatment, and in addition, they receive "functional proprioceptive stimulations" (FPS) on the lower limbs (i.e., synchronized tendon vibration applied to the lower limbs). They receive 30-minute PFS sessions four times a week, from inclusion to discharge. FPS are delivered with the Vibramoov® system (Techno Concept, Manosque, France) by a trained physiotherapist. This system consists of twelve vibrators attached to the patients with the help of orthoses and controlled by a computer via Bluetooth. Treatment begins as soon as the physician in charge of the patient considers the patient clinically stable.

Patients are randomized according to a permuted block randomization scheme with a block size of 8. Moreover, patients are stratified into two groups according to the presence or absence of a central nervous system lesion.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vibramoov® system

Primary outcome measure
Functional status measured using the Physical Function in ICU Test-scored (PFIT-s) at discharge from the ICU

Secondary outcome measures
1. Cognitive impairments measured using the Montreal cognitive assessment (MoCA) at discharge from the ICU and 3 months after discharge
2. Anxiety and depressive disorders measured using the Hospital anxiety and depression scale (HADS) at discharge from the ICU and 3 months after discharge
3. PTSD symptoms measured using the PTSD Checklist for DSM-5 (PCL-5) at discharge from the ICU and 3 months after discharge
4. Functional status measured using the Physical Function in ICU Test-scored (PFIT-s) 8 to 10 days from admission in the ICU and upon awakening
5. Functional status measured using the ICU Mobility Scale (IMS) upon awakening and on discharge from the ICU
6. Functional independence measured using the Barthel Index at discharge from the ICU and 3 months after discharge
7. Correlations between functional tests (PFIT-s, IMS, Barthel Index) and cognitive tests (MoCA, HAD, PCL-5) measured using Pearson or Spearman coefficients using the timepoints defined
8. Muscular strength measured using the Medical Research Council-Sum Score (MRC-SS) and with a dynamometric measure of the quadriceps strength upon awakening and then once a week until discharge from the ICU
9. Changes in the quadriceps muscle thickness measured using ultrasound at inclusion, at 4 days post-inclusion, at 10 days post-inclusion, and then once a week until discharge from the ICU
10. Changes in the rectus femoris cross-section measured using ultrasound at inclusion, at 4 days post-inclusion, at 10 days post-inclusion, and then once a week until discharge from the ICU
11. Changes in the rectus femoris echogenicity measured using ultrasound at inclusion, at 4 days post-inclusion, at 10 days post-inclusion, and then once a week until discharge from the ICU
12. Changes in the spasticity measured using the modified Ashworth scale (MAS) and the modified Tardieu scale (MTS) on discharge from the ICU (only for patients with a central nervous system lesion)
13. Number of delirium days in ICU measured using the Confusion Assessment Method for ICU (CAM-ICU)
14. Number of days ventilation-free in the first 28 days in ICU measured using patient medical records at one timepoint at the end of the study
15. Incidence of ICU-Acquired Weakness (ICU-AW), diagnosed by an MRC-SS < 48/60, measured using patient medical records at one timepoint at the end of the study
16. Length of ICU stay measured in days using patient medical records at one timepoint at the end of the study
17. Length of hospital stay measured in days using patient medical records at one timepoint at the end of the study
18. Mortality rate in hospital at 3 months and 6 months measured using patient medical records at one timepoint at the end of the study

Overall study start date
30/05/2022

Completion date
30/05/2024

Eligibility

Key inclusion criteria
1. Adult (≥ 18 years old)
2. Hospitalised in the intensive care unit (ICU)
3. At least 48 hours of mechanical ventilation
4. Functionally independent two weeks before the admission to ICU (Barthel Index ≥ 70, estimated by interviewing relatives)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Hospitalised in ICU for more than 5 days
2. Hyperacute phase (absence of hemodynamic balance)
3. Orthopedic injury preventing the implementation of the protocol
4. Serious psychiatric or cognitive history
5. Irreversible disorder with a 6-month mortality greater than 50% or patient with a probable fatal outcome in the ICU
6. Rapidly progressive neuromuscular disease
7. Spinal cord injury
8. Severe traumatic brain injury (Glasgow Coma Scale score ≤ 8)
10. Known pregnancy
11. Patients with phlebitis
12. Patients with active devices such as pacemakers, defibrillators, insulin pumps, neurostimulators, etc.
13. Patients with cardiac arrhythmia
14. Patients with epilepsy
15. Patients with fragile skin or open wounds
16. Not affiliated with the French social security system
17. Patients who speak neither French nor English
18. Persons deprived of liberty and under legal protection

Date of first enrolment
27/02/2023

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
France

Study participating centre
Hôpital Bicêtre
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Sponsor information

Organisation
Association MAPAR (Mise Au Point Anesthésie Réanimation)

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Sponsor type
University/education

Website
https://www.mapar.org/

Funder(s)

Funder type
University/education

Funder Name

Association MAPAR (Mise Au Point Anesthésie Réanimation)

Funder Name
TechnoConcept

Funder Name
Assistance Publique - Hôpitaux de Paris/Public Assistance Hospital of Paris

Alternative Name(s)
Assistance Publique Hôpitaux de Paris, Assistance Publique–Hôpitaux de Paris, AP-HP

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
France

Funder Name
Association Nationale Recherche Technologie/National Association for Research in Technology

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0	14/12/2022	14/03/2023	No	No