STEPS To ICU Recovery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20691

Source
Nationaal Trial Register

Brief title
STEPS Study

Health condition

Critical illness, early mobilisation, intensive care, ICU-aquired weakness, ambulation.

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam (AMC]
Source(s) of monetary or material Support: Amsterdam UMC, location AMC - Innovation Grant.

Intervention

Outcome measures

Primary outcome

The primary objective is to investigate the effect of BWSTT in critically ill patients on time to functional ambulation

Secondary outcome

The secondary objectives of this study are to investigate the effects on other patient relevant outcome measures for the evaluation of BWSTT. These outcomes are walking capacity, walking distance, muscle strength, ICU acquired weakness, symptoms of post-traumatic stress, experienced exertion after physiotherapy (PT) intervention, training intensity (i.e. respiratory frequency, heart rate, blood pressure and oxygen saturation) of PT interventions, status of functional independency, functional ambulation, duration of mechanical ventilation, (Serious) Adverse Events), number of staff needed, time spent on intervention and patient satisfaction.

Study description

Background summary

Intensive Care Unit (ICU) acquired weakness results in difficult weaning from the ventilator and impedes functional recovery. Body weight supported treadmill training (BWSTT) has shown to be an effective modality for improving fitness, walking capacity and daily functioning in different populations but not for critically patients in an ICU. Our previous study showed that BWSTT is safe and feasible in an ICU setting. In this trial the effectiveness of BWSTT for critically ill patients in an ICU will be evaluated.

Study objective

Body weight-supported treadmill training during ICU and hospital stay leads to earlier independent functional ambulation compared to usual care.

Study design

Measurements of the primary outcome will be performed daily on the ICU en the regular wards but not on the weekends.

Intervention

ParticIpants who are randomized into the lntervention group will receive BWSTT in addition to usual care. The BWSST intervention consists of walking on a treadmill while supported by a hamess. The intervention will be conducted according to the standardized operating procedure inciuding safety checks, transfers,
bodyweight support, treadmill speed and ambulation duration. The training will be inltiated during ICU stay and conducted by two experienced ICU physlotherapists, one who Is lnvolved in !hls study and a (intensive care or ward) physiotherapist who Is not involved in the study. BWSTT is provided on a daily basis (5 times a week, not during the weekend) in the ICU and continued on regular ward until a patient is able to ambulate with walking aid and physical support for balance assistance.

Contacts

Public
Postbus 22660
Marike van der Schaaf
Afdeling Revalidatie, Academisch Medisch Centrum, Universiteit van Amsterdam
Amsterdam 1100 DD
The Netherlands
020-5664421
Scientific
Postbus 22660
Marike van der Schaaf
Afdeling Revalidatie, Academisch Medisch Centrum, Universiteit van Amsterdam
Amsterdam 1100 DD
The Netherlands
020-5664421

Eligibility criteria

Inclusion criteria

Admission at ICU for medica! or surgical reasons, age 2:18, Mechanica! ventilatlon 2:48 hours, Meeting safety critiria vor rehabilitation according to the Evidence Statement for ICU physiotherapy (Sommers, 2016)

Exclusion criteria

Not meeting the safety criteria for rehabilitation according to the evidence statement for ICU physiotherapy. Imminent to death. Insufficient knowledge of the Dutch language. Unable to walk in the month prior to ICU admission. Neurological diseases and disorders as reason for ICU admission. One or more amputated lower extremities. Mental retardation

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-12-2017
Enrollment:	88
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-12-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48582
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6766
NTR-old	NTR6943
CCMO	NL63104.018.17
OMON	NL-OMON48582

Study results