Steps to Recovery: Body-weight-supported treadmill training for patients in the intensive care unit: a randomized controlled trial

Published: 12-03-2018
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The objective of this study is to investigate the effect of BWSTT in critically ill patients on time to independent functional ambulation as compared to usual care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON48582

Source
ToetsingOnline

Brief title
Steps to Recovery

Condition

- Muscle disorders

Synonym
Critical illness, Intensive Care Unit-Acquired Weakness (ICU-AW)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Intensive Care, Physical Therapy, Rehabilitation, Walking capacity

Outcome measures

Primary outcome

The number of days to independent ambulation as measured with the Functional Ambulation Categories (FAC *3).

The FAC is recorded daily as part of physiotherapy treatment.

Secondary outcome

The following parameters are recorded as part of daily physiotherapy care and will be used as secundairy outcome measures: walking distance, overall muscle strength, fatigue after physiotherapy, physiological response to exercise (heart rate, respiratory frequency, blood pressure, saturation), functional status, walking capacity, duration of treatment, number of staff needed, duration of mechanical ventilation, ICU acquired weakness, time to start of walking training..

The following parameters will be recorded additionally to usual care for the purpose of this study: anxiety, pain and satisfaction (numeric rating scale) and symptoms of post traumatic stress (PCL-5).

Study description

Background summary

Every year more than 85.000 patients are admitted to Dutch Intensive Care Units (ICU's). Many patients develop ICU acquired weakness. ICU-AW is associated with prolonged mechanical ventilation, poor functional recovery, prolonged hospital stay en decreased quality of life after hospital discharge. Decreased walking

capacity may exist for years after a stay in the ICU.
The departments of Rehabilitation and Intensive Care Medicine developed in collaboration with Motek ForceLink a prototype transportable treadmill with weight bearing facility. This novel technology enables ICU patients with muscle weakness to walk at the bedside without interuption of medical treatment (ventilation, dialysis, medication etc) and monitoring of vital signs.
Our pilot study showed that body weight supported treadmill training is feasible and safe in ICU patients.

Study objective

The objective of this study is to investigate the effect of BWSTT in critically ill patients on time to independent functional ambulation as compared to usual care.

Study design

A randomized controlled trial

Intervention

Participants who are randomized into the intervention group will receive BWSTT in addition to usual care. The BWSST intervention consists of walking on a treadmill while supported by a harness. The intervention will be conducted according to the standardized operating procedure including safety checks, transfers, bodyweight support, treadmill speed and ambulation duration. The training will be initiated during ICU stay and conducted by two experienced ICU physiotherapists, one who is involved in this 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 (FAC 2 or higher).

When the BWSTT intervention is stopped (FAC 2 or higher), physiotherapy as usual care will be provided from that point on.

Study burden and risks

Moderate risk due to the use of a medical device. Our pilot study demonstrated that BWSTT is feasible and safe in critically ill intenisive care patients. No additional risk to usual physiotherapy for ICU patients.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Admission at ICU for medical or surgical reasons, age *18, Mechanical ventilation *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 (protocol page 7; exclusion criteria)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2018
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Transportable Treadmill with weighbearing utility
Registration:	No

Ethics review

Approved WMO Date:	12-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20691
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63104.018.17
Other	NTR: 6943
OMON	NL-OMON20691