

STEPS To ICU Recovery

Gepubliceerd: 01-12-2017 Laatste bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20691

Bron

Nationaal Trial Register

Verkorte titel

STEPS Study

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam (AMC]

Overige ondersteuning: Amsterdam UMC, location AMC - Innovation Grant.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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 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 initiated during ICU stay and conducted by two experienced ICU physlotherapists, one who Is Involved 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.

Contactpersonen

Publiek

Postbus 22660
MARIKE van der Schaaf
Afdeling Revalidatie, Academisch Medisch Centrum, Universiteit van Amsterdam
Amsterdam 1100 DD

The Netherlands
020-5664421

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Admission at ICU for medical or surgical reasons, age 2:18, Mechanical ventilation 2:48 hours, Meeting safety criteria for rehabilitation according to the Evidence Statement for ICU physiotherapy (Sommers, 2016)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind

Controle: Geneesmiddel

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 08-12-2017
Aantal proefpersonen: 88
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 01-12-2017
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48582
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten