The impact of nUrsiNg DEliRium Preventive INterventions in the Intensive Care Unit: A study protocol for a multi-centre, stepped wedge randomized controlled trial

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Implementation of standardized multi component intervention package tailored to ICU patients which focusses on reducing modifiable delirium risk factors by nursing and physical therapy interventions

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

Samenvatting

ID

NL-OMON24866

Bron
NTR

Verkorte titel
UNDERPIN-ICU

Aandoening

Delirium

Ondersteuning

Primaire sponsor: Radboud University Medical Center
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of delirium-coma-free days in 28 days

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Delirium is a common disorder in Intensive Care Unit (ICU) patients and is associated with serious short- and long-term consequences, including re-intubations, ICU readmissions, prolonged ICU and hospital stay, persistent cognitive problems, and higher mortality rates. Considering the high incidence of delirium and its consequences, prevention of delirium is imperative. This study focuses on a program of standardized nursing and physical therapy interventions to prevent delirium in the ICU, called UNDERPIN-ICU (nUrsiNg DEliRium Preventive INterventions in the ICU).

Objective: To determine the effect of the UNDERPIN-ICU program on the number of delirium-coma-free days in 28 days and several secondary outcomes, such as delirium incidence, the number of days of survival in 28 and 90 days and delirium-related outcomes.
Design and setting: A multicenter stepped wedge cluster randomized controlled trial.

Methods: Eight to ten Dutch ICUs will implement the UNDERPIN-ICU program in a randomized order. Every two months the UNDERPIN-ICU program will be implemented in an additional ICU following a two months period of staff training. UNDERPIN-ICU consists of standardized protocols focusing on several modifiable risk factors for delirium, including cognitive impairment, sleep deprivation, immobility and visual and hearing impairment.

Participants: ICU patients aged 18 years (surgical, medical, or trauma) and at high risk for delirium, E-PREDELIRIC ≥35%, will be included, unless delirium was detected prior ICU admission, expected length of ICU stay is less then one day or when delirium assessment is not possible.

Doel van het onderzoek

Implementation of standardized multi component intervention package tailored to ICU patients which focusses on reducing modifiable delirium risk factors by nursing and physical therapy interventions

Onderzoeksopzet

Days 0, 28, 90 and 365 after admission

Onderzoeksproduct en/of interventie

The UNDERPIN-ICU program consists of interventions tailored for ICU patients focusing on the modifiable delirium risk factors: visual and hearing impairment, to prevent or treat sensory deprivation and ultimately the loss of orientation; sleep deprivation, to minimize/avoid sleep deprivation; cognitive impairment to (re)orientate patients with regard to time, place and person to prevent or minimize decline; and immobility, to improve patients¡¯ functional mobility in the ICU and to stimulate patients¡¯ cognition.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult (¡Ý 18 years); surgical, medical or trauma patients; admitted to one of the participating ICUs and at high risk for delirium (>35% determined with the E-PRE-DELIRIC prediction tool)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

delirious before ICU admission; have an ICU stay < one day; if reliable assessment for delirium is not possible due to: sustained coma during complete ICU stay; serious auditory or visual disorders; inability to understand Dutch; severely mentally disabled; serious receptive aphasia.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	31-12-2016
Aantal proefpersonen:	1750
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6172
NTR-old	NTR6319
Ander register	METC Arnhem-Nijmegen : 2013/173

Resultaten