

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

No registrations found.

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

Summary

ID

NL-OMON24866

Source

NTR

Brief title

UNDERPIN-ICU

Health condition

Delirium

Sponsors and support

Primary sponsor: Radboud University Medical Center

Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

delirium incidence; the number of days of survival in 28 and 90 days; delirium-related outcomes including: duration of mechanical ventilation, incidence of re-intubation, or restart of mechanical ventilation in case of tracheostomy patients, incidence of ICU re-admission, unplanned removal of tubes/catheters, and the use of physical restraints; ICU and hospital length of stay; QoL and cognitive function of ICU patients at ICU admission (baseline), and three and twelve months after ICU discharge; an exploratory subgroup analyses (e.g. based on admission type, predicted delirium risk); a process evaluation to explain the effects based on adherence to the interventions; and a cost-effectiveness analysis which will include an economic evaluation.

Study description

Background summary

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 $\geq 35\%$, will be included, unless delirium was detected prior ICU admission, expected length of ICU stay is less than one day or when delirium assessment is not possible.

Study objective

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

Study design

Days 0, 28, 90 and 365 after admission

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

Adult (≥ 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)

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	31-12-2016
Enrollment:	1750
Type:	Anticipated

Ethics review

Positive opinion	
Date:	25-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results