Dynamic light application to prevent acquired delirium

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1. To evaluate the feasibility and safety of dynamic light application in an Intensive Care facility2. To study the effects of dynamic light application on the incidence of delirium, the number of ICU and hospital days and mortality in a mixed...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON36549

Source
ToetsingOnline

Brief title
Dynamic light application in ICU patiens

Condition

- Deliria (incl confusion)

Synonym
delirium; acute confusional state; confusion

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Jeroen Bosch Ziekenhuis

Intervention

Keyword: confusion, delirium, dynamic light, light therapy

Outcome measures

Primary outcome

incidence of delirium as measured by the CAM-ICU

Secondary outcome

ICU and total hospital mortality

ICU and hospital LOS

ventilation duration

Study description

Background summary

Delirium is a frequently encountered problem in ICU patients and leads to increased morbidity and mortality; Delirium in the ICU is associated with sleep deprivation which is among others caused by a disrupted circadian rhythm; Dynamic Light application aims at restoring a proper circadian rhythm by rhythmically alternating light intensity and has shown beneficial effects in sleep quality. Whether DLA improves sleep quality and reduces delirium incidence in ICU patients is not known

Study objective

1. To evaluate the feasibility and safety of dynamic light application in an Intensive Care facility
2. To study the effects of dynamic light application on the incidence of delirium, the number of ICU and hospital days and mortality in a mixed population of medical and surgical ICU patients
3. To determine whether severity of disease influences treatment effect and outcome

Study design

prospective randomized single centre trial

Intervention

Patients will be randomized between Standard Care or Standard Care + DLA; When receiving standard care, normal lighting settings will be used in that patient room, which can be controlled by the medical personel; In the rooms of patients randomized to the DLA group, DL is applied with a changing intensity during the day according to a fixed rhythm, which is regulated centrally. In addition when necessary, an intervention light can be used which can be operated in the patient room.

Study burden and risks

The extent of the burden is nil for the subjects: as well as the risks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

ICU patients>18 years old
expected duration of stay on ICU >24 hrs

Exclusion criteria

diagnosis of delirium before admission at ICU
Preexisting cognitive impairment
life expectancy of less than 48 hours on ICU admission
blindness
unability to speak or understand dutch

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2011
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	31-01-2011
Application type:	First submission

Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-07-2011
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-09-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
Other	DLA 11
CCMO	NL34780.028.10