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The effect of earplugs during the night on the onset of delirium and sleep perception in intensive care patients

Submission date
11/11/2011

Recruitment status
No longer recruiting

Registration date
09/12/2011

Overall study status
Completed

Last Edited
11/12/2015

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Delirium is a state of mental confusion that can happen if you become medically unwell. It is a common complication in the intensive care unit (ICU). The aim of this study is to find out whether delirium can be prevented in ICU patients by using earplugs at night.

Who can participate?
Adult patients staying for at least one night in the intensive care department of the Antwerp University Hospital.

What does the study involve?
Participants are randomly allocated either to wear earplugs overnight or to not wear earplugs overnight. Delirium and sleep quality are assessed on the following morning.

What are the possible benefits and risks of participating?
The intervention did not interfere with the treatment or standard ICU care. No risks were expected.

Where is the study run from?
University of Antwerp (Belgium).

When is the study starting and how long is it expected to run for?
November 2008 to April 2010.

Who is funding the study?
University of Antwerp (Belgium).

Who is the main contact?
1. Prof dr P Jorens
2. Prof dr B Van Rompaey (bart.vanrompaey@ua.ac.be)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of earplugs during the night on the onset of delirium and sleep perception in intensive care patients: an observational study

Study objectives
Sleeping with earplugs during the night lowers the prevalence of delirium and confusion in intensive care patients. Also, sleep perception will improve.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical board of the Antwerp University hospital, November 2008, ref: 8/40/223

Study design
Single-center observational randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Delirium in intensive care patients

Interventions
The researchers screened all intensive care patients on a daily basis to invite eligible patients to the study. After giving informed consent, an independent nurse researcher assigned the patients to the study group or the control group. Next, a nontransparent canister holding earplugs or a dummy was positioned at the bedside of the patient. Tthe critical care nurse opened the cannister at 22.00 hr and positioned the earplugs when present. A second assignment at 06.00 hr asked the critical care nurse to remove the earplugs from the patient and to keep them in the closed canister again. When the canister contained a dummy instead of earplugs, no action was undertaken. Patients and staff were instructed not to report on wearing earplugs or not during the night to the researchers. One of the blinded researchers visited the patients during the morning to assess them for delirium and sleep perception.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Delirium was assessed using the Neelon and Champagne Confusion Scale (NEECHAM)
1.1. The NEECHAM is based on the nurses' twenty-four hour assessment of the level of processing information, the level of behavior and the physiological condition rating the patient on a 30-0 scale. Next, the results can be classified in one of four categories. The cut-off values, 30-27 'normal', 26-25 'at risk', 24-20 'early to mild confusion' (mild confusion) were standardized. The scores 19-0 'moderate to severe confusion' show delirium in the studied patient.
2. Sleep perception was assessed using five dichotomous questions on the self reported sleep quality of the patient:
2.1. Did you sleep well?
2.2. Did you sleep better as expected?
2.3. Did you sleep better than at home?
2.4. Were you awake for a long time before falling asleep?
2.5. Do you feel sufficiently rested? The score on question four was reversed. A higher total sum score on the five questions showed a better sleep perception.

Secondary outcome measures

No secondary outcome measures

Overall study start date
21/11/2008

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. Adult (18 year or older)
2. The expected length of stay in the intensive care unit (ICU) was over 24 hours
3. Dutch or English speaking
4. Scoring a minimum Glasgow Coma Scale of 10

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
When the use of earplugs could lower the incidence of 'delirium or confusion' with 20%, a power of 0.80 and á=0.05 showed that 46 patients in each group had to be included

Key exclusion criteria
1. Patients with known hearing impairment
2. Dementia
3. Confusion or delirium at admittance
4. Also, sedation was used as a exclusion criterion to optimize the assessment of delirium and sleep perception

Date of first enrolment
21/11/2008

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Belgium

Study participating centre
University of Antwerp
Antwerp
Belgium
2610

Sponsor information

Organisation
University of Antwerp (Belgium)

Sponsor details
Faculty of Medicine and Healthcare
Division of Nursing Science and Midwifery
Universiteitsplein 1
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Belgium
2610

Sponsor type
University/education

Website
http://www.ua.ac.be/

ROR
https://ror.org/008x57b05

Funder(s)

Funder type
University/education

Funder Name
University of Antwerp (Belgium)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/05/2012		Yes	No