

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

<b>Submission date</b> 11/11/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/12/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/12/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## Contact name

Prof Bart Van Rompaey

## Contact details

Universiteitsplein 1

Gebouw R 3.30

Antwerp

Belgium

2610

-

bart.vanrompaey@ua.ac.be

# Additional identifiers

## Protocol serial number

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

## Study type(s)

Treatment

## 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. The critical care nurse opened the canister 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(s)**

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.

## **Key secondary outcome(s)**

No secondary outcome measures

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

**ROR**

<https://ror.org/008x57b05>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Antwerp (Belgium)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	04/05/2012		Yes	No