

Ear plugs helpful for children admitted to an intensive care?

Gepubliceerd: 28-04-2017 Laatste bijgewerkt: 18-08-2022

We hypothesize that wearing earplugs on busy periods in the PICU can reduce the level of distress.

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

Samenvatting

ID

NL-OMON22537

Bron

NTR

Aandoening

Stress caused by noise

Ondersteuning

Primaire sponsor: Prof. dr. D. Tibboel

Overige ondersteuning: Erasmus MC Sophia, Rotterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in COMFORT-B score between before and after the intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Wearing earplugs during noisy periods in the Intensive Care Unit have shown a positive effect in neonates and adults. Evidence in critically ill children is lacking.

Objective: To determine the effect of using earplugs during busy hours in the PICU on level of distress assessed with the COMFORT-B scale.

Study design: Open randomized control trial, stratified by age group.

Study population: Children from 0 to 18 years with the expectation of at least two nights admitted to the PICU.

Intervention: The intervention group wears earplugs during three standard periods of the day with peak intensity of noise and activity in the PICU.

Main study parameters/endpoints: 1) Difference in COMFORT-behaviour score before and after the intervention. 2) Heart rate before, during and after the intervention. 3) Incidence and duration of delirium in intervention group compared with the control group. 4) Use of sedatives in intervention group and control group. 5) Sleep pattern.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants will be visited six times a day. The intervention group will not experience more burden than wearing earplugs three times a day and have six site visits each day by the researcher to insert or remove the earplug. The researcher will measure the COMFORT-B score at the same site visits.

According to research in neonates and adults, earplugs have a positive effect on vital signs and delirium, so we expect these effects for the current intervention group as well. This current study needs to be done in this population because the lack of research about earplugs in this population.

Doel van het onderzoek

We hypothesize that wearing earplugs on busy periods in the PICU can reduce the level of distress.

Onderzoeksopzet

The patients will wear the earplugs three periods a day: 8.00-10.00, 14.00-16.00, 18.00-20.00.

- COMFORT-B score: before and after each period of wearing the earplugs.
- Heart rate: before and after each period of wearing the earplugs.

- All other secondary outcomes: three times a day by the care giving nurse.

Onderzoeksproduct en/of interventie

Wearing earplugs during busy periods in the PICU.

Contactpersonen

Publiek

[default]

The Netherlands

Wetenschappelijk

[default]

The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria:

- Expected length of stay in PICU of at least 2 nights
- Parental consent and if possible assent of the child from the age of twelve

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria:

- Severe deafness

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2017
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	28-04-2017
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	NL6236
NTR-old	NTR6416
Ander register	METC : MEC-2017-219

Resultaten