

Sleep ICU healthy subjects

Gepubliceerd: 26-10-2016 Laatst bijgewerkt: 18-08-2022

Environmental disturbances during ICU submission may explain observed EEG-arousals

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

Samenvatting

ID

NL-OMON22713

Bron

NTR

Aandoening

Disturbed sleep, verstoerde slaap

Ondersteuning

Primaire sponsor: Philips Research Eindhoven

Overige ondersteuning: Department of Critical Care, University Medical Center Groningen, Rijksuniversiteit Groningen
Philips Research Eindhoven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sleep related parameters: number of arousals and awakenings per hour, total sleep time, sleep efficiency, sleep continuity

Toelichting onderzoek

Achtergrond van het onderzoek

Patients admitted to an intensive care unit (ICU) are exposed to several intrinsic and extrinsic sleep disruptive factors, causing disturbed sleep, which may have detrimental effects on patient cognition and behavior. Because so many factors play a role, studying the primary effects of the busy ICU environment is complicated in patients and can therefore best be done in healthy volunteers.

Little is known about the importance of individual intrinsic and extrinsic factors on sleep in the ICU. This study will investigate the role of sound, light, and the inherent experience of the ICU environment on the incidence of arousals, and therefore the continuity of sleep. Focusing on the study of healthy subjects eliminates confounding and immeasurable intrinsic factors present in patients, that may interfere with clear analysis of this relation.

Doel van het onderzoek

Environmental disturbances during ICU submission may explain observed EEG-arousals

Onderzoeksproduct en/of interventie

The sleep quantity and quality of the subjects will be measured during 3 nights using polysomnography. Subjects will sleep 1 night at home, 1 night in a closed section of the ICU and 1 night in the active ICU.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy volunteers (nurses/doctors(in training)) currently not employed on the ICU

Age \geq 18 years

Capable of understanding and speaking Dutch

Normal hearing

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pre-existing history or treatment of sleep pathology

Sleep promoting medication

Alcohol addiction or illicit drug abuse

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-12-2016
Aantal proefpersonen: 10
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 26-10-2016
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	NL6050
NTR-old	NTR6189
Ander register	: METc 2016/468

Resultaten