The reliability of event detection in parasomnia by the monitoring of heart rate changes.

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To evaluate if an event (changes of heart frequency) related video-observation is a more efficient diagnostic procedure for parasomnias.

Ethical review	Approved WMO
Status	Pending
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON30157

Source
ToetsingOnline

Brief title
Parasomnia

Condition

- Sleep disturbances (incl subtypes)

Synonym
parasomnia, sleep disorder

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: zorgverzekeraars

Intervention

Keyword: event detection, heart rate, parasomnia

Outcome measures

Primary outcome

Reliability, sensitivity and specificity of the detection of parasomnic events.

Secondary outcome

Comparison of event related detection with an one night polysomnography

combined with videorecording; value of SCID and MMIP tests for the mental

background of parasomnia.

Study description

Background summary

Parasomnia (attacks with abnormal behavior during sleep) can only be found by polysomnography in combination with video recordings. This is a complicated procedure that can be applied only during one or two nights. Parasomnic attacks are often infrequent, so the current procedure is nog sufficient. In this project we try to record parasomnic events more effectively.

Study objective

To evaluate if an event (changes of heart frequency) related video-observation is a more efficient diagnostic procedure for parasomnias.

Study design

An open explorative study during which in ten persons with parasomnia a 'seizure detector' is applied during five nights. This detector sends an alarm if heart rate is specifically accelerated. Digital video-information around the alarms is stored, inspected and compared with a traditional polysomnography including video recording. We also obtain some questionnaires / interviews to get an impression of the mental situation of the persons. This is important for the final diagnosis of the type of parasomnia.

Study burden and risks

The burden of the study is a five-nights long hospital admission with nocturnal videorecording; every night three electrodes are applied for the detection of heart rate; during one night a polysomnography will be carried out (with multiple electrodes and sensors); finally the various questionnaires / interviews are a burden. The risks are small (skin reactions on the electrodes, reactions on privacy disturbances).

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

between 18 and 60 years of age

a body mass index between 18 and 30
suffering from NREM 3-4 and/or REM parasomnia
minimal parasomnia frequency: 2 / week
no acute behavioral problems, except as a part of RBD
no acute intercurrent somatic disease that may interfere with study results
informed consent form signed
adult

Exclusion criteria

epilepsy
major or significant internal or neurological that interfere with teh measurements
ESS score > 10/24
fast progressing neurological and / or systematic disorder
pregnancy
drugs or pacemakers that significantly influence hart rate
inability to comply with the trial procedure
inability to tolerate ECG electrodes
presence of manifest psychiatric disorders
below normal intelligence

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-04-2006
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL12210.068.06