The effect of low doses of mirtazapine and quetiapine on sleep and daytime functioning.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40193

Source
ToetsingOnline

Brief title
mirtazapine, quetiapine and sleep

Condition

- Other condition

Synonym
sleep disorder, sleeplessness

Health condition

insomnie

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Drenthe (Assen)
Source(s) of monetary or material Support: NWO (aanvraag ingediend),GGZ Drenthe

Intervention

Keyword: functioning, mirtazapine, quetiapine, sleep

Outcome measures

Primary outcome

Sleep polysomnography and subjective sleep.

Secondary outcome

Daytime sleepiness and daytime cognitive functioning.

Study description

Background summary

Sleep complaints are common in the general population and, even more so, among psychiatric patients. People suffering from poor sleep may experience problems falling asleep, maintaining sleep, waking up too early in the morning and/or non refreshing sleep. These sleep problems often result in daytime sleepiness and considerable functional impairment. Medication prescribed to alleviate sleep disturbances, such as benzodiazepines, rapidly produce tolerance and physical dependency and should therefore be used for short time periods or intermittently. Consequently, clinicians worldwide routinely prescribe a low dose of sedative antidepressants like mirtazapine and/or antipsychotics, particularly quetiapine. This is remarkable, in view of the limited knowledge on the effects of these substances on sleep and daytime performance. Objective studies validating this clinical practice are therefore necessary.

Study objective

The primary goal of this study is to investigate the effect of low doses of mirtazapine and quetiapine on sleep, assessed using polysomnography and subjective sleep measures, of healthy subjects whose sleep will be disturbed by auditory stimuli (situational insomnia). Additionally, possible hangover effects that may hamper daytime functioning will be examined, that is, daytime

sleepiness and decreased cognitive functioning.

Study design

For this randomized, double-blind, placebo-controlled, cross-over study, 25 healthy, male participants will be recruited. They will stay at the sleep centre in Assen for three sets of three consecutive nights, one set for each experimental condition, that is (1) mirtazapine, (2) quetiapine, and (3) placebo. Sleep recordings (polysomnography) will be made during all nights, subjective sleep, daytime sleepiness and cognitive functioning will be measured during the day using questionnaires, two cognitive tasks, a psychomotor vigilance task and a sleep latency test. After a wash-out period of four days, the protocol will be repeated, until each participant participated in all experimental conditions.

Intervention

Participants will stay at the sleep centre for three sets of three consecutive nights. Before going to sleep on the second and third night, participants will take either 7.5 mg mirtazapine, 50 mg quetiapine or placebo. During each third night, participants will additionally exposed to auditory stimuli, an ongoing recording of traffic noise, to experimentally induce (situational) insomnia.

Study burden and risks

In order to objectify the sleep promoting effects of low doses of mirtazapine and quetiapine in healthy participants without sleep disturbances, sleep will be disturbed during the night by acoustic stimuli. Although it can be experienced as a nuisance, the procedure poses no risk for the participants. During the study, participants each take two doses of 7,5 mg mirtazapine, 50 mg quetiapine and a placebo (night two and three). On the basis of previous research on these drugs, the low doses used in this study and the fact that each drug is only taken twice by each participant, the study is considered to be of minimal risk to participants.

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

Non-smoking, male, between the ages of 18 and 35 years.

Exclusion criteria

Past or present sleeping disorder and/or psychiatric disorder, a family history of sleeping disorder and/or psychiatric disorder, liver disease, cardiovascular disease, alcohol- or substance dependence, medication use (including psychotropic medication), known intolerance for mirtazapine or quetiapine, a BMI of or below 18.5 or of or above 30.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2014
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Remeron
Generic name:	Mirtazapine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Seroquel
Generic name:	Quetiapine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	06-12-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	03-03-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	17-12-2014
Application type:	Amendment

Review commission: METC Isala Klinieken (Zwolle)

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
EudraCT	EUCTR2013-003460-31-NL
CCMO	NL46501.075.13