ISRCTN20011041 https://doi.org/10.1186/ISRCTN20011041

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

**Submission date**
30/03/2016

**Recruitment status**
No longer recruiting

**Registration date**
31/03/2016

**Overall study status**
Completed

**Last Edited**
29/01/2019

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Sleep is an essential requirement for life, and is vital for people to be able to function. Many people in the general population have trouble falling or staying asleep, or do not feel refreshed after sleeping. Around 30% of otherwise healthy people experience these kinds of sleep difficulties (insomnia) and in those suffering from mental health problems, this number is even higher. Insomnia is often treated using sedatives (benzodiazepines), however these are very addictive and can have unwanted side effects, such as feeling tired and sleepy during the day. In many cases, low doses of alternative drugs which have sedating properties are prescribed, such as mirtazapine (antidepressant), or quetiapine (antipsychotic medication). Although many doctors observe improvement in patients treated this way, there are few studies which support the effectiveness of low doses of mirtazapine or quetiapine for the treatment of insomnia. The aim of this study is to investigate the effects of 7.5mg mirtazapine and 50mg quetiapine on sleep and daytime functioning.

Who can participate?
Healthy men aged between 18 and 35 who usually go to bed between 10pm and midnight and sleep between 6.5 to 8.5 hours a night.

What does the study involve?
Participants sleep at the sleep center of GGZ Drenthe on three consecutive nights, for three consecutive weeks. Each week participants take a different medication, the order of which is random. Night one of each week is considered an adaptation night, when participants can adapt to sleeping in the unfamiliar surroundings. On nights two and three of each week, participants are asked to take a capsule containing 7.5mg mirtazapine, 50mg quetiapine, or a placebo (dummy pill) 30 minutes before they go to bed. During the night, participants have their sleep monitored by a machine that records brain waves, blood oxygen levels, heart rate, breathing and eye and leg movement (polysomnography). Each morning, participants are asked to fill out questionnaires about their quality of sleep and current sleepiness and complete tasks on a computer which measure their reaction time (movement associated with mental processes).

What are the possible benefits and risks of participating?
There are no direct benefits of taking part although participants will receive financial

compensation. There is a small risk of experiencing side effects from the study medications, such as sleepiness during the day or dizziness.

Where is the study run from?
GGZ Drenthe (Netherlands)

When is the study starting and how long is it expected to run for?
January 2014 to September 2015

Who is funding the study?
GGZ Drenthe (Netherlands)

Who is the main contact?
Dr Julie Karsten

# Contact information

### Type(s)
Scientific

### Contact name
Dr Julie Karsten

### Contact details
GGZ Drenthe
Dennenweg 9
Assen
Netherlands
9404 LA

# Additional identifiers

### EudraCT/CTIS number
2013-003460-31

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
NL46501.075.13

# Study information

### Scientific Title
The effect of 7.5 mg mirtazapine and 50 mg quetiapine, compared to placebo, on situational insomnia and daytime functioning in healthy male subjects

### Study objectives

7.5 mg mirtazapine or 50 mg quetiapine improve situational insomnia, without affecting daytime functioning.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Regional ethics board METC Isala Zwolle, 03/03/2014, ref: 13.11138

## Study design
Single-centre double blind cross-over study

## Primary study design
Interventional

## Secondary study design
Randomised cross over trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Insomnia

## Interventions
Participants attend the study centre on consecutive nights, for three consecutive weeks and receive the study treatments in a random order. The first night of the study is an adaption night and the study medication is taken 30 minutes before bed on the second and third night. During sleep, participants are monitored using polysomnography. Participants are interviewed 15 minutes and two hours after waking to assess sleep quality and daytime sleepiness.

Study treatments:
7.5 mg mirtazapine
50 mg quetiapine
Placebo

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
1. Mirtazapine 2. Quetiapine

### Primary outcome measure
1. Sleep quality is measured using polysomnography during each night
2. Subjective sleep is measured by the Leeds Sleep Evaluation Questionnaire (LSEQ) 15 minutes after waking

### Secondary outcome measures
1. Daytime sleepiness is measured by the Karolinska Sleepiness Scale (KSS) 2 hours after waking
2. Daytime cognitive functioning is measured by the Psychomotor Vigilance Task (PVT) and the Digit Symbol Substitution Task (DSST) 2 hours after waking

### Overall study start date
01/01/2014

### Completion date
02/09/2015

## Eligibility

### Key inclusion criteria
1. Male
2. Aged between 18-35 years
3. BMI between 18.0-30 kg/m2
4. Absence of clinically relevant health problems
5. History of going to bed from 22.00h to 00.00h on at least 5-7 nights per week, with a reported sleep duration of 6.5-8.5h over the previous 3 months before the start of and during the study

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
35 Years

### Sex
Male

### Target number of participants
19

### Key exclusion criteria
1. History of sleep disorder or psychiatric illness
2. Family history of sleep disorder or psychiatric disorder
3. Liver disease
4. Cardiovascular disease

5. Alcohol or drug dependence
6. Use of (psychotropic) medication
7. Known intolerance for either mirtazapine or quetiapine

### Date of first enrolment
01/09/2014

### Date of final enrolment
01/05/2015

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**GGZ Drenthe**
Dennenweg 9
Assen
Netherlands
9404 LA

## Sponsor information

### Organisation
GGZ Drenthe

### Sponsor details
Dennenweg 9
Assen
Netherlands
9404 LA

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/0107rkg57

## Funder(s)

### Funder type
Industry

### Funder Name
GGZ Drenthe

### Alternative Name(s)
Geestelijke Gezondheidszorg Drenthe

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
Netherlands

## Results and Publications

### Publication and dissemination plan
1. Planned publication of study results in a peer reviewed journal
2. Planned dissemination of findings at national and international conferences

### Intention to publish date
01/09/2016

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/03/2017 | 29/01/2019 | Yes | No |