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Serotonin sensitivity in insomnia: a placebo-controlled crossover study of sleep after 5HT2 blockade in primary insomnia

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0038183440

Study information

Scientific Title

Serotonin sensitivity in insomnia: a placebo-controlled crossover study of sleep after 5HT2 blockade in primary insomnia

Study objectives
Does Trazodone improve sleep in primary insomnia?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bath Research Ethics Committee, 21/04/2006, REC ref: 06/Q2001/32.

Study design
Randomised double-blind placebo-controlled crossover study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nervous System Diseases: Primary insomnia

Interventions
Trazodone vs placebo.
Overnight sleep patterns recorded and compared, after either placebo or trazodone 100mg. Each patient has screening visit and 2 overnight sleep recordings at home a week apart, plus an end-of study visit.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Trazodone

Primary outcome(s)
Sleep efficiency: % Total Sleep Time / Staging Time.

Key secondary outcome(s))
1. Daily symptom report (DSR)
2. Total sleep time (TST)
3. Number of awakenings
4. Wake Time After Sleep Onset (WASO)
5. Time spent in stages 1 to 4 and rapid eye movement (REM), %TST spent in each stage
6. REM onset latency
7. Sleep onset Latency (SOL), slow wave activity
8. Leeds Sleep Evaluation Questionnaire.

Completion date
31/01/2009

Eligibility

Key inclusion criteria
1. Adults referred to Psychopharmacology Unit Clinic 7, Bristol Royal Infirmary with psycho-physiological insomnia
2. Complaint of poor sleep with daytime consequences

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
12

Key exclusion criteria
1. Taking psychotropic medication
2. Total sleep time (subjective) < 6.5 hours
3. Current psychiatric disorder

Date of first enrolment
28/04/2006

Date of final enrolment
31/01/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Bristol
Bristol
United Kingdom
BS1 3NY

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Avon and Wiltshire Mental Health Partnership NHS Trust (UK)

Funder Name
AWP Partnership Mental Health NHS Trust R&D Project grant

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	conference abstract	01/09/2009	21/06/2019	No	No
Other publications	review article	01/09/2011	21/06/2019	Yes	No