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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Sleep efficiency: % Total Sleep Time / Staging Time.

Secondary outcome measures
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.

Overall study start date
28/04/2006

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

Age group
Adult

Sex
Both

Target number of participants
12 insomnia patients

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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