

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	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/06/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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