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Impact of nefazodone on sleep architecture in insomnia

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/09/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

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
N0038104044

Study information

Scientific Title
Impact of nefazodone on sleep architecture in insomnia

Study objectives
Does nefazodone improve sleep in insomnia?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Insomnia

Interventions
1. Nefazodone
2. Placebo

This is a double blind placebo-controlled crossover study to look at the effects of nefazodone on sleep in insomnia. Patients will be given a two week washout from any psychotropic medication and then randomised to take either 100 mg of nefazodone or placebo for 2 weeks with a 2 week washout, then cross over to the treatment. At the end of the each 2 weeks their overnight sleep will be measured at home by polysomnography and they will be asked to fill in questionnaires about their sleep. Objective and subjective sleep measures will be compared in subject between the two treatment periods.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Objective Total Sleep Time
2. Subjective Sleep Quality

Secondary outcome measures
All other measures of objective and subjective sleep

Overall study start date
01/10/2001

Completion date
30/09/2003

Eligibility

Key inclusion criteria
Patients aged 18 to 65 meeting criteria for insomnia (International Classification of Sleep Disorders) and without: use of other psychotropic drugs, allergy to nefazodone, current or past severe mental illness or substance abuse, current depressive illness.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2001

Date of final enrolment
30/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Cottham House
Bristol
United Kingdom
BS16 1JB

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

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

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