ISRCTN84604889 https://doi.org/10.1186/ISRCTN84604889

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
1. Objective Total Sleep Time
2. Subjective Sleep Quality

Key secondary outcome(s)
All other measures of objective and subjective sleep

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Cottham House
Bristol
United Kingdom
BS16 1JB

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration