

# Impact of nefazodone on sleep architecture in insomnia

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 28/09/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jane Hicks

**Contact details**  
Cottham House  
Cottham Hill  
Bristol  
United Kingdom  
BS16 1JB  
+44 (0)117 9 427 373  
abc@123.com

## 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