

# Efficacy of prolonged-release melatonin versus placebo in a three-week treatment of diabetic patients suffering from insomnia

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| <b>Submission date</b><br>25/02/2009   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>27/02/2009 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>27/02/2009       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
|  |  | <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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
Neu951005

# Study information

## Scientific Title

A randomised double-blind, crossover study comparing the efficacy of prolonged-release melatonin versus placebo in a three-week treatment of diabetic patients suffering from insomnia

## Study objectives

Type 2 uncontrolled diabetic patients often have low endogenous melatonin and suffer from sleep disorders. The effect of a prolonged-release melatonin (PRM) formulation on glucose lipid metabolism and sleep is studied in type 2 diabetes patients with insomnia.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of the E. Wolfson Medical Centre Holon, approved on 01/11/1995 (ref: 5471)

## Study design

Randomised double-blind placebo-controlled crossover trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Type 2 diabetes mellitus, insomnia

## Interventions

In a randomised, double-blind, crossover study, the subjects were treated for 3 weeks with 1 tablet per night of 2 mg prolonged-release melatonin (Circadin®) (oral) or placebo, with one week washout period in between.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome measure

Sleep efficiency (Time Frame: 3 weeks). Efficacy of sleep quality was objectively monitored by a wrist actigraphy device (Somnitor™). Sleep efficiency is the percentage of time patients were asleep while in bed as scored by the actigraphic sleep algorithm.

### **Secondary outcome measures**

Safety. Total duration of follow-up: 3 weeks

### **Overall study start date**

01/11/1995

### **Completion date**

01/03/1997

## **Eligibility**

### **Key inclusion criteria**

Independently living male and female patients (no age limits) who complained of insomnia and suffer from diabetes.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

36

### **Key exclusion criteria**

Patients with liver or renal problems (serum creatinine above 1.5 mg/dL).

### **Date of first enrolment**

01/11/1995

### **Date of final enrolment**

01/03/1997

## **Locations**

### **Countries of recruitment**

Israel

### **Study participating centre**

**Neurim Pharmaceuticals Ltd.**  
Tel Aviv  
Israel  
69710

## **Sponsor information**

### **Organisation**

Neurim Pharmaceuticals Ltd. (Israel)

### **Sponsor details**

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### **Sponsor type**

Industry

### **Website**

<http://www.neurim.com>

### **ROR**

<https://ror.org/01gd1jq14>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Neurim Pharmaceuticals Ltd. (Israel)

## **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