

# Levetiracetam for Treatment of Non-psychotic and Non-depressive behavioural symptoms of dementia

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|--|---|--|
| <b>Submission date</b><br>28/12/2006   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>28/12/2006 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>28/12/2006       | <b>Condition category</b><br>Mental and Behavioural Disorders | <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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

### Acronym

LaTiNN

### Study objectives

Specific behavioural symptoms of dementia needs specific treatment. In cases, levetiracetam seems to be effective in non-psychotic and non-depressive behavioural symptoms of dementia.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local medical ethics committee

### Study design

Non-randomised, clinical trial

### Primary study design

Interventional

### Secondary study design

Single-centre

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

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

Dementia

### Interventions

500 mg Levetiracetam/day to a maximum 1500 mg Levetiracetam/day.

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

Levetiracetam

### **Primary outcome measure**

Effect on week four and 13 compared to base-line on:

1. Behavioural symptoms (NPI and Cohen-Mansfield Agitation Inventory [CMAI])
2. Care-giver burden (CBI)
3. Clinical impression (Global Clinical Impression [GCI])

### **Secondary outcome measures**

Effect on week four and 13 compared to base-line on:

1. Cognition (Mini Mental State Examination [MMSE])
2. Activities in Daily Living (ADL) (Interview for Deterioration in Daily living activities in Dementia [IDDD])

### **Overall study start date**

01/08/2006

### **Completion date**

01/04/2007

## **Eligibility**

### **Key inclusion criteria**

1. Ambulant patients with dementia, level Reisberg four to six
2. Informant available
3. Six weeks stable treatment of dementia, anti-psychotics and anti-depressants

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

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

25

### **Key exclusion criteria**

1. Neuropsychiatric Inventory (NPI) item hallucinations, delusions and depression more than one
2. Epilepsia
3. Alcoholism
4. Diabetes Mellitus (DM) or thyroid disease not under control

### **Date of first enrolment**

01/08/2006

### **Date of final enrolment**

01/04/2007

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

### Jeroen Bosch Hospital

Den Bosch

Netherlands

5200 ME

# Sponsor information

## Organisation

Jeroen Bosch Hospital (The Netherlands)

## Sponsor details

Department of Geriatrics

P.O. Box 1101

Den Bosch

Netherlands

5200 BD

## Sponsor type

Hospital/treatment centre

## Website

[http://www.jeroenboschziekenhuis.nl/jbz/jbz\\_patient](http://www.jeroenboschziekenhuis.nl/jbz/jbz_patient)

## ROR

<https://ror.org/04rr42t68>

# Funder(s)

## Funder type

Not defined

## Funder Name

Not provided at time of registration

# 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/06/2005   |            | Yes            | No              |