

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

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/12/2006	Condition category 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
Dr P L J Dautzenberg

Contact details
Jeroen Bosch Hospital
Department of Geriatrics
P.O. Box 90153
Den Bosch
Netherlands
5200 ME
+31 (0)73 699 8629
p.dautzenberg@jbz.nl

Additional identifiers

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

Primary study design

Interventional

Study design

Non-randomised, clinical trial

Study type(s)

Treatment

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(s)

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])

Key secondary outcome(s)

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])

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

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

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

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?
Results article		01/06/2005		Yes	No