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

Submission date	Recruitment status
28/12/2006	No longer recruiting
Registration date	**Overall study status**
28/12/2006	Completed
Last Edited	**Condition category**
28/12/2006	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

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

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?
Results article		01/06/2005		Yes	No