

Efficacy and tolerability of levetiracetam in central post-stroke pain - a randomised, double blind, placebo controlled, cross-over study

Submission date 11/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/02/2023	Condition category Circulatory System	<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

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Additional identifiers

Study information

Scientific Title
Efficacy and tolerability of levetiracetam in central post-stroke pain - a randomised, double blind, placebo controlled, cross-over study

Acronym

LESS

Study objectives

Levetiracetam has a positive pain relief effect in patients with central post stroke pain and is well tolerated.

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Central poststroke pain (CPSP)

Interventions

The study is based on a cross over design. Each randomised patient will receive 8 weeks of Levetiracetam and 8 weeks of placebo in blinded order. The medication periods consist of a 4 week titration phase starting with 1000 mg/day (14 days) to 2000 mg/day (14 days) and followed by 4 weeks of a constant dose of 3000 mg/day.

Pain diary based on NRS, lab test, cerebral magnetic resonance imaging (MRI), neurological examination including extended sensibility and sensory testing, questionnaires, drug administration.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Levetiracetam

Primary outcome(s)

Primary endpoint is a reduction of two points in the median pain intensity on a scale 0 (no pain) to ten (maximum pain) assessed by the patient during the last week of treatment with 3000 mg levetiracetam or placebo compared to the median pain intensity assessed in the second pre-treatment baseline week.

Key secondary outcome(s)

Secondary endpoints are the median pain scale during the last week of treatment with 1000 mg and 2000 mg levetiracetam or placebo. Further secondary endpoints are the results of the clinical sensory and pain assessment and the results of the NRS (Numeric Rating Scale), Beck Depression Inventory, the SF36 (Short Form-36 Health Survey (Quality of Life) as well as the PSQI (Pittsburgh Sleep Quality Index).

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Age >18 years
2. Central Post Stroke Pain >3 months
3. Previous ischaemic or haemorrhagic stroke >3 months
4. Pain intensity >4 on numeric rating scale (NRS)
5. Rankin Score <2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

42

Key exclusion criteria

1. Dementia or other severe cognitive impairment
2. Diabetic neuropathy
3. Epilepsy
4. Severe pain other than central poststroke pain
5. Malignant disease
6. Recent myocardial infarction
7. Severe heart insufficiency
8. Severe liver or renal failure
9. Severe hematological disease
10. Prior treatment with or known allergy to levetiracetam
11. Positive history for alcohol or for drug abuse
12. Pregnancy or lactation
13. Participation in a clinical study within two months of screening

Date of first enrolment

01/10/2004

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Germany

Study participating centre

Klinik für Neurologie

Berlin

Germany

10117

Sponsor information

Organisation

Individual Sponsor (Germany)

Funder(s)

Funder type

Industry

Funder Name

Charité - University Medicine Berlin (Charité - Univeritätsmedizin Berlin) (Germany)

Funder Name

Berlin Neuroimaging Centre (Germany)

Funder Name

UCB Pharma Belgium (Belgium)

Funder Name

UCB GmbH Kerpen (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		01/02/2013	23/02/2023	Yes	No