ISRCTN38932730 https://doi.org/10.1186/ISRCTN38932730

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/06/2005	**Overall study status** Completed	
Last Edited 23/02/2023	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gerhard Jan Jungehülsing

Contact details
Klinik für Neurologie
Charité Campus Mitte
Schumannstr. 20/21
Berlin
Germany
10117
+49 30 450 560 145
jan.junge-huelsing@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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 Inventary, the SF36 (Short Form-36 Health Survey (Quality of Life) as well as the PSQI (Pittsburgh Sleep Quality Index).

Overall study start date
01/10/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

49

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 failiure
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)

Sponsor details
Dr Gerhard Jan Jungehülsing
Klinik für Neurologie

Charité Campus Mitte
Schumannstr. 20/21
Berlin
Germany
10117
+49 30 450 560 145
jan.junge-huelsing@charite.de

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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