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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
11/05/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
07/06/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
23/02/2023	Circulatory System			

## 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

# 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 pretreatment 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

#### 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