

HEAD-to-head evaluation of the antiepileptic drugs, levetiracetam versus sulthiame in a German multicentre, double-blind, controlled trial in children with benign epilepsy with centrotemporal spikes

Submission date 16/09/2005	Recruitment status Stopped	☐ Prospectively registered
		☐ Protocol
Registration date 21/04/2006	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 29/09/2008	Condition category Nervous System Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Florian Heinen

Contact details
Abteilung für Pädiatrische Neurologie und Entwicklungsneurologie
Dr. von Haunersches Kinderspital
Lindwurmstr. 4
München
Germany
80337
+49 (0)89 5160 7851
florian.heinen@med.uni-muenchen.de

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00471744

Protocol serial number

HEAD-STUDIE

Study information

Scientific Title

Acronym

HEAD

Study objectives

Added as of 29/09/2008: Please note that this trial has been prematurely terminated on 01/07/2008 due to insufficient recruitment.

Hypothesis:

We hypothesise that levetiracetam (LEV) is as effective as sulthiame (STM) in the treatment of children with benign epilepsy with centrottemporal spikes (BECTS)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval not yet received as of 21/04/06

Primary study design

Interventional

Study design

Multicentre, double-blind, randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Benign epilepsy of childhood with centrottemporal spikes (BECTS)

Interventions

Patients entering the HEAD-STUDIE are either treated with levetiracetam or sulthiame over a six-month period. Patients are equally randomised to one of the two treatment regimens.

Administration of medication as blinded capsules.

Please note that as of 08/05/2007 the anticipated start and end dates of this trial have now been updated to the following:

Anticipated start date: 01/06/2006

Anticipated end date: 31/12/2007

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Levetiracetam and sulthiame

Primary outcome(s)

To evaluate the efficacy of levetiracetam in the treatment of children with BECTS compared to sulthiame

Key secondary outcome(s)

1. Safety and tolerability
2. Efficacy on EEG pattern
3. Cognitive effects

Completion date

30/06/2007

Reason abandoned (if study stopped)

Insufficient recruitment

Eligibility

Key inclusion criteria

1. Age between 6 and 12 years
2. Weight between 15 kg and 60 kg
3. At least two preceding seizures within the last six months before study start
4. Typical electroencephalogram (EEG) with Rolando focus (centrotemporal spike or sharp-wave-focus)
5. Diagnosis of BECTS
6. Written informed consent from parents and child (≥ 8 years)

Inclusion criteria added/changed as of 08/05/2007:

1. Age between 5 and 14 years
2. Weight between 15 kg and 60 kg
3. At least two preceding seizures within the last six months before study start
4. Typical electroencephalogram (EEG) with Rolando focus (centrotemporal spike or sharp-wave-focus)
5. Diagnosis of BECTS
6. Written informed consent from parents and child (≥ 8 years)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Years

Upper age limit

12 Years

Sex

All

Key exclusion criteria

1. Other forms of epilepsy (e.g. continuous spikes and waves during slow sleep [CSWS], Landau-Kleffner-syndrome)
2. Preceding treatment with antiepileptic drugs
3. Mental Retardation (intelligence quotient [IQ] <85)
4. Focal neurological deficit
5. Relevant major internistic disease (e.g. hepatopathy, nephropathy, endocrinopathy)
6. Participation in another clinical trial within the last 30 days

Date of first enrolment

01/01/2006

Date of final enrolment

30/06/2007

Locations**Countries of recruitment**

Germany

Study participating centre

Abteilung für Pädiatrische Neurologie und Entwicklungsneurologie

München

Germany

80337

Sponsor information**Organisation**

Hospital of the University of Munich, Dr. von Haunerschen Childrens Hospital (Germany)

Funder(s)**Funder type**

Industry

Funder Name

Funded by UCB Pharma GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration