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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/04/2006	**Overall study status** Stopped	
Last Edited 29/09/2008	**Condition category** Nervous System Diseases	

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
NCT00471744

Secondary identifying numbers
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 centrotemporal spikes (BECTS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval not yet received as of 21/04/06

Study design
Multicentre, double-blind, 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
Benign epilepsy of childhood with centrotemporal 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 measure
To evaluate the efficacy of levetiracetam in the treatment of children with BECTS compared to sulthiame

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

Overall study start date
01/01/2006

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

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
120

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)

Sponsor details
Lindwurmstr. 4
München
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
Funded by UCB Pharma GmbH (Germany)

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