Clinical trial results:
HEAD-TO-HEAD evaluation of the antiepileptic drugs Levetiracetam (LEV) vs. Sulthiame (STM) in a German multi-centre, doubleblind controlled trial in children with benign epilepsy with centro-temporal spikes

Summary

EudraCT number	2005-004468-22
Trial protocol	DE
Global end of trial date	01 October 2008

Results information

Result version number	v1 (current)
This version publication date	02 September 2021
First version publication date	02 September 2021

Trial information

Trial identification

Sponsor protocol code	HEAD-STUDIE

Additional study identifiers

ISRCTN number	ISRCTN97864911
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dr. von Haunersches Kinderspital München
Sponsor organisation address	Lindwurmstr. 4, Munich, Germany, 80337
Public contact	Dr. von Haunersches Kinderspital München, Dr. von Haunersches Kinderspital München, 89 440052811,
Scientific contact	Dr. von Haunersches Kinderspital München, Dr. von Haunersches Kinderspital München, 49 89440052811,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 October 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2008
Global end of trial reached?	Yes
Global end of trial date	01 October 2008
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the HEAD-STUDIE is to evaluate the efficacy of levetiracetam in the treatment of children with BECTS compared to sulthiame

Protection of trial subjects:

Routine care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 44
Worldwide total number of subjects	44
EEA total number of subjects	44

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	44
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

47 German study centers

Pre-assignment

Screening details:

Screening for 28 days

Period 1

Period 1 title	Dosage adjustment
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Levetiracetam

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Levetiracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use

Dosage and administration details:

Dosage increase to 30 mg/kg*d

Arm title	Sulthiame

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Sulthiame
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use

Dosage and administration details:

6 mg/kg*d

Number of subjects in period 1	Levetiracetam	Sulthiame
Started	22	22
Completed	22	22

Period 2	
Period 2 title	Observation
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms	
Are arms mutually exclusive?	Yes
Arm title	Levetiracetam
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Levetiracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details: Dosage increase to 30 mg/kg*d	
Arm title	Sulthiame
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Sulthiame
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details: 6 mg/kg*d	

Number of subjects in period 2	Levetiracetam	Sulthiame
Started	22	22
Completed	13	19
Not completed	9	3
Adverse event, non-fatal	5	1
Lack of efficacy	4	2

Baseline characteristics

Reporting groups	
Reporting group title	Dosage adjustment

Reporting group description: -

Reporting group values	Dosage adjustment	Total	
Number of subjects	44	44	
Age categorical Units: Subjects			
Children (2-11 years)	44	44	
Gender categorical Units: Subjects			
Female	16	16	
Male	28	28	

End points

End points reporting groups

Reporting group title	Levetiracetam
Reporting group description: -	
Reporting group title	Sulthiame
Reporting group description: -	
Reporting group title	Levetiracetam
Reporting group description: -	
Reporting group title	Sulthiame
Reporting group description: -	

Primary: Treatment failure

End point title	Treatment failure
End point description:	
End point type	Primary
End point timeframe:	
Observation period	

End point values	Levetiracetam	Sulthiame		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	22		
Units: Patients	4	2		

Statistical analyses

Statistical analysis title	Treatment failure
Comparison groups	Levetiracetam v Sulthiame
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.412
Method	Fisher exact

Secondary: Dropout due to adverse events

End point title	Dropout due to adverse events
End point description:	
End point type	Secondary

End point timeframe:
Observation period

End point values	Levetiracetam	Sulthiame		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	22		
Units: Patients	5	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Whole study	
Assessment type	Systematic

Dictionary used	
Dictionary name	Custom
Dictionary version	x

Reporting groups	
Reporting group title	Levetiracetam
Reporting group description: -	
Reporting group title	Sulthiame
Reporting group description: -	

Serious adverse events	Levetiracetam	Sulthiame	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0		
Psychiatric disorders			
Suicidal thoughts			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Levetiracetam	Sulthiame	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 22 (100.00%)	22 / 22 (100.00%)	
Cardiac disorders			
Cardiac			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	0	
Nervous system disorders			
CNS			

subjects affected / exposed	13 / 22 (59.09%)	16 / 22 (72.73%)	
occurrences (all)	13	16	
General disorders and administration site conditions			
General			
subjects affected / exposed	15 / 22 (68.18%)	17 / 22 (77.27%)	
occurrences (all)	15	17	
Other			
subjects affected / exposed	4 / 22 (18.18%)	5 / 22 (22.73%)	
occurrences (all)	4	5	
Gastrointestinal disorders			
Gastrointestinal			
subjects affected / exposed	10 / 22 (45.45%)	8 / 22 (36.36%)	
occurrences (all)	10	8	
Respiratory, thoracic and mediastinal disorders			
Airways			
subjects affected / exposed	5 / 22 (22.73%)	14 / 22 (63.64%)	
occurrences (all)	5	14	
Psychiatric disorders			
Behavior			
subjects affected / exposed	13 / 22 (59.09%)	13 / 22 (59.09%)	
occurrences (all)	22	22	
Musculoskeletal and connective tissue disorders			
Bones and muscles			
subjects affected / exposed	4 / 22 (18.18%)	4 / 22 (18.18%)	
occurrences (all)	4	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported