Clinical trial results:
A Multicenter, Open-Label, Single-Arm Study to Evaluate Long-Term Safety, Tolerability, and Efficacy of Brivaracetam in Study Participants 2 to 26 Years of Age With Childhood Absence Epilepsy or Juvenile Absence Epilepsy

Summary

EudraCT number	2020-002769-33
Trial protocol	HU BE IT PL SK Outside EU/EEA RO ES
Global end of trial date	18 March 2025

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	EP0132

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05109234
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	UCB BIOSCIENCES GmbH, Clin Trial Reg & Results Disclosure, clinicaltrials@ucb.com
Scientific contact	UCB BIOSCIENCES GmbH, Clin Trial Reg & Results Disclosure, clinicaltrials@ucb.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000332-PIP02-17
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 April 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 March 2025
Global end of trial reached?	Yes
Global end of trial date	18 March 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study is to investigate the long-term safety, tolerability and efficacy of brivaracetam (BRV) in pediatric study participants with childhood absence epilepsy (CAE) or juvenile absence epilepsy (JAE).

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator: -

Actual start date of recruitment	30 March 2022
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	Georgia: 39
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Romania: 17
Country: Number of subjects enrolled	Slovakia: 3
Country: Number of subjects enrolled	Ukraine: 4
Country: Number of subjects enrolled	United States: 14
Worldwide total number of subjects	84
EEA total number of subjects	27

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)	55

Adolescents (12-17 years)	29
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in March 2022 and concluded in March 2025.

Pre-assignment

Screening details:

The Participant Flow refers to the Safety Set (SS). Participants who participated in N01269 (NCT04666610) were offered participation in this study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Childhood Absence Epilepsy (CAE): Brivaracetam

Arm description:

Participants with CAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of CAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV, FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Arm type	Experimental
Investigational medicinal product name	Brivaracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Brivaracetam tablet dose of 100 mg/day (or equivalent doses of 2 mg/kg/day for participants weighing <50 kg). Dose may be adjusted after 3 days from 50-200 mg/day (or equivalent dose of 1-4 mg/kg/day for participants <50 kg) based on individual needs. Maximum allowed daily dose was 200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).

Arm title	Juvenile Absence Epilepsy (JAE): Brivaracetam

Arm description:

Participants with JAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of JAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV,FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Arm type	Experimental

Investigational medicinal product name	Brivaracetam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Brivaracetam tablet dose of 100 mg/day (or equivalent doses of 2 mg/kg/day for participants weighing <50 kg). Dose may be adjusted after 3 days from 50-200 mg/day (or equivalent dose of 1-4 mg/kg/day for participants <50 kg) based on individual needs. Maximum allowed daily dose was 200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).

Number of subjects in period 1	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam
Started	64	20
Evaluation Period (Up to 24 months)	64	20
Completed	50	14
Not completed	14	6
Consent withdrawn by Participant (not due to AE)	1	-
Adverse event, non-fatal	2	2
Consent withdrawn by parent/guardian (not AE)	3	4
Evacuated from Ukraine due to the war	2	-
Missed safety visit;study incomplete per protocol	1	-
Lack of efficacy	5	-

Baseline characteristics

Reporting groups

Reporting group title	Childhood Absence Epilepsy (CAE): Brivaracetam

Reporting group description:

Participants with CAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of CAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV, FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Reporting group title	Juvenile Absence Epilepsy (JAE): Brivaracetam

Reporting group description:

Participants with JAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of JAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV,FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Reporting group values	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam	Total
Number of subjects	64	20	84
Age Categorical Units: participants			
24 months - <12 years	53	2	55
12 - <18 years	11	18	29
Age Continuous Units: years			
arithmetic mean	9.56	13.93	
standard deviation	± 2.49	± 1.64	-
Sex: Female, Male Units: participants			
Female	37	11	48
Male	27	9	36

End points

End points reporting groups

Reporting group title	Childhood Absence Epilepsy (CAE): Brivaracetam

Reporting group description:

Participants with CAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of CAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV, FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Reporting group title	Juvenile Absence Epilepsy (JAE): Brivaracetam

Reporting group description:

Participants with JAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of JAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV,FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Primary: Percentage of Participants With Treatment Emergent Adverse Events (TEAEs)

End point title	Percentage of Participants With Treatment Emergent Adverse Events (TEAEs)[1]

End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study medication, whether or not considered related to the study medication. TEAEs are defined as AEs that had onset on or after the day of first dose of BRV. The SS consisted of all enrolled study participants who took at least 1 dose of study drug in the long-term follow-up (LTFU) study.

End point type	Primary

End point timeframe:

From Entry Visit up to 16.32 months (median); min, max exposure to BRV was (0.4, 31.0) months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	20		
Units: percentage of participants				
number (not applicable)	42.2	55.0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with TEAEs Leading to Discontinuation of Study Treatment

End point title	Percentage of Participants with TEAEs Leading to Discontinuation of Study Treatment[2]

End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study medication, whether or not considered related to the study medication. TEAEs are defined as AEs that had onset on or after the day of first dose of BRV. Percentage of participants with TEAEs leading to discontinuation were reported. The SS consisted of all enrolled study participants who took at least 1 dose of study drug in the LTFU study.

End point type	Primary

End point timeframe:

From Entry Visit up to 16.32 months (median); min, max exposure to BRV was (0.4, 31.0) months

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	20		
Units: percentage of participants				
number (not applicable)	3.1	10.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Serious TEAEs

End point title	Percentage of Participants with Serious TEAEs

End point description:

TEAEs are defined as AEs that had onset on or after the day of first dose of BRV. A Serious Adverse Event (SAE) is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires in patient hospitalization or prolongation of existing hospitalization, is a congenital anomaly or birth defect, results in permanent or significant disability/incapacity, other important medical events which based on medical or scientific judgement may jeopardize the patients, or may require medical or surgical intervention to prevent any of the above. The SS consisted of all enrolled study participants who took at least 1 dose of study drug in the LTFU study.

End point type	Secondary

End point timeframe:

From Entry Visit up to 16.32 months (median); min, max exposure to BRV was (0.4, 31.0) months

End point values	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	20		
Units: percentage of participants				
number (not applicable)	3.1	10.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Study Drug-related TEAEs

End point title	Percentage of Participants with Study Drug-related TEAEs

End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study medication, whether or not considered related to the study medication. TEAEs are defined as AEs that had onset on or after the day of first dose of BRV. Drug related AEs are the subset of AEs that the investigator considers as related to the study drug. The SS consisted of all enrolled study participants who took at least 1 dose of study drug in the LTFU study.

End point type	Secondary

End point timeframe:

From Entry Visit up to 16.32 months (median); min, max exposure to BRV was (0.4, 31.0) months

End point values	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	20		
Units: percentage of participants				
number (not applicable)	6.3	10.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Absence Seizure Freedom Within 4 Days Prior to or During the 1-hour Electroencephalogram (EEG)

End point title	Percentage of Participants with Absence Seizure Freedom

	Within 4 Days Prior to or During the 1-hour Electroencephalogram (EEG)

End point description:

A 1-hour EEG was performed. The awake hours from the EEG was analyzed for absence seizures. Every 1-hour EEG included hyperventilation as a standard provocation test at the beginning of the EEG. Participant was regarded as not meeting the criteria for absence seizure freedom if they received any permitted antiepileptic drugs including benzodiazepine in the 4 days prior to the EEG or during the EEG. Participants who continue in the study beyond 2 years have their data truncated at Year 2 Month 24 yearly evaluation visit (YEV). The SS consisted of all enrolled study participants who took at least 1 dose of study drug in the LTFU study. Here, number of participants analyzed 'N' included all participants who were evaluable for this assessment and 'n' signifies participants who were evaluable at each specified timepoints.

End point type	Secondary

End point timeframe:

Full Evaluation Visit (6 months), Yearly Evaluation Visit (12 months), Full Evaluation Visit (18 months), Yearly Evaluation Visit (24 months)

End point values	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	20		
Units: percentage of participants				
number (not applicable)				
FEV: 6 months (n= 56, 20)	46.4	70.0		
YEV: 12 months (n=47, 18)	42.6	44.4		
FEV: 18 months (n=36, 16)	38.9	50.0		
YEV: 24 months (n=30, 11)	26.7	18.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Absence Seizure Freedom Based on Daily Seizure Diary Over the Entire Evaluation Period and by 3-month Time Intervals

End point title	Percentage of Participants with Absence Seizure Freedom Based on Daily Seizure Diary Over the Entire Evaluation Period and by 3-month Time Intervals

End point description:

During the study, participants kept diary to record daily seizure activity from entry visit (Visit 1) until final visit. Each seizure type experienced were recorded. Participant was considered as not meeting criteria for absence seizure freedom if they use any permitted anti-epileptic drugs at any time during the period, and/or complete less than 80% of diaries during the period. Evaluation Period includes all daily seizure diary data over Evaluation Period up to Month 24 YEV, this includes data from end of Months 22 to 24 up to Month 24 YEV where this data is truncated. If a participant does not attend Month 24 YEV then data was truncated at last day participant is in Evaluation Period in Month 24 YEV window. Participants who continue in study beyond 2 years have their data truncated at Year 2 Month 24 YEV, or last day participant was in Evaluation Period in Month 24 YEV window if this visit is not attended. The SS was used. 'n' =participants evaluable at each specified timepoints.

End point type	Secondary

End point timeframe:

Months 1-3, Months 4-6, Months 7-9, Months 10-12, Months 13-15, Months 16-18, Months 19-21,

End point values	Childhood Absence Epilepsy (CAE): Brivaracetam	Juvenile Absence Epilepsy (JAE): Brivaracetam		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	20		
Units: percentage of participants				
number (not applicable)				
Months 1-3(n=64,20)	34.4	35.0		
Months 4-6(n=59,20)	39.0	55.0		
Months 7-9(n=53,19)	37.7	57.9		
Months 10-12(n=49,18)	38.8	55.6		
Months 13-15(n=44,18)	31.8	61.1		
Months 16-18(n=39,16)	35.9	56.3		
Months 19-21(n=33,14)	30.3	42.9		
Months 22-24(n=32,12)	21.9	33.3		
Entire Evaluation Period(up to 24 months)(n=64,20)	28.1	30.0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Entry Visit up to 16.32 months (median); min, max exposure to BRV was (0.4, 31.0) months

Adverse event reporting additional description:

Treatment-emergent adverse events were defined as AEs that had onset on or after the day of first dose of BRV. The Safety Set (SS) consisted of all enrolled study participants who took at least 1 dose of study drug in the LTFU study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Juvenile Absence Epilepsy (JAE): Brivaracetam

Reporting group description:

Participants with JAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of JAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV, FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Reporting group title	Childhood Absence Epilepsy (CAE): Brivaracetam

Reporting group description:

Participants with CAE entered Evaluation Period to receive BRV, tablet or oral solution dose of 100 mg/day(or equivalent doses of 2 mg/kg/day for participants weighing <50 kg).Dose could be adjusted after 3 days from 50-200 mg/day(or equivalent dose of 1-4 mg/kg/day for participants <50 kg)based on individual needs.Maximum allowed daily dose =200 mg/day (or equivalent dose of 4 mg/kg/day for participants <50 kg).Duration per participant was 2 years minimum,until approval of BRV for indication of CAE was obtained for pediatric participants in their age range,until MAP was established as allowed per country-specific requirements and legal/regulatory guidelines, or until investigational product development in related indication is stopped by Sponsor, whichever come first. Participants transitioned to another BRV study EP0224(NCT06315322)/MAP/similar program/who convert to commercial BRV, FV instead of EDV needed; down-titration(dose reduction to half during 4 weeks); SV not applicable.

Serious adverse events	Juvenile Absence Epilepsy (JAE): Brivaracetam	Childhood Absence Epilepsy (CAE): Brivaracetam	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 20 (10.00%)	2 / 64 (3.13%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 20 (5.00%)	0 / 64 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Status epilepticus			
subjects affected / exposed	1 / 20 (5.00%)	0 / 64 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 64 (1.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	0 / 20 (0.00%)	1 / 64 (1.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Measles			
subjects affected / exposed	1 / 20 (5.00%)	0 / 64 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Juvenile Absence Epilepsy (JAE): Brivaracetam	Childhood Absence Epilepsy (CAE): Brivaracetam	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 20 (40.00%)	15 / 64 (23.44%)	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 20 (10.00%)	3 / 64 (4.69%)	
occurrences (all)	3	4	
Petit mal epilepsy			
subjects affected / exposed	5 / 20 (25.00%)	9 / 64 (14.06%)	
occurrences (all)	8	10	
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 5	4 / 64 (6.25%) 4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 September 2020	Protocol Amendment 1 was dated 08 Sept 2020. The purpose of this substantial amendment was to remove all decentralized study components as it was decided that all participant visits will occur on site. Centrally read 24-hour electroencephalogram (EEGs) were removed; locally read 1-hour EEGs that reflect normal clinical practice will be used in this study. In addition, the Conners Continuous Performance Tests (CPT), Achenbach Childhood Behavior Checklist (CBCL), and EuroQol 5- Dimension (EQ-5D) Quality of Life Assessments have been removed from the list of participantand caregiver-reported outcomes and the wearable EEG (SeizeIT) substudy has been removed.
29 March 2021	Protocol Amendment 2 was dated 29 Mar 2021. The purpose of this substantial amendment was to address Health Authority feedback, correct minor errors/inconsistencies, provide additional clarifying information.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

EP0132 enrolled fewer participants than expected (approximately 140) so it was closed prematurely, followed by initiation of managed access program EP0225 (NCTID not applicable) and its replacement with the new open-label study EP0224 (NCT06315322).

Notes: