EU Clinical Trials Register

Clinical trial results:
An Open-Label Study With an Extension Phase to Evaluate the Pharmacokinetics of Perampanel (E2007) Oral Suspension When Given as an Adjunctive Therapy in Subjects From 1 Month to Less Than 4 years of Age With Epilepsy

Summary

EudraCT number	2013-005391-17
Trial protocol	LV
Global end of trial date	25 April 2023

Results information

Result version number	v1
This version publication date	08 November 2023
First version publication date	08 November 2023

Trial information

Trial identification

Sponsor protocol code	E2007-G000-238

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02914314
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eisai Ltd.
Sponsor organisation address	European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, United Kingdom, AL10 9SN
Public contact	EMEA Medical Information, Eisai Ltd., +44 (0)208 600 1400, EUMedInfo@eisai.net
Scientific contact	EMEA Medical Information, Eisai Ltd., +44 (0)208 600 1400, EUMedInfo@eisai.net

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000467-PIP01-08
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	25 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to evaluate the pharmacokinetics (PK) of perampanel during the Maintenance Period of the Core Study following oral suspension administration given as an adjunctive therapy in pediatric subjects from 1 month to less than 4 years of age with epilepsy.

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures (SOPs) of the sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following: - Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008) - International Council on Harmonisation (ICH) E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board (IRB) regulations and applicable sections of US 21 CFR Part 312 - European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions were reported, as required, to the Competent Authorities of all involved EU member states. - Article 14, Paragraph 3, and Article 80-2 of the Pharmaceutical Affairs Law (Law No. 145, 1960) for studies conducted in Japan, in addition to Japan's GCP Subject Information and Informed Consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 February 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Latvia: 7
Country: Number of subjects enrolled	United States: 14
Worldwide total number of subjects	21
EEA total number of subjects	7

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)	18
Children (2-11 years)	3
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:

Subjects took part in the study at 8 investigative sites in the United States and Latvia from 20 February 2017 to 25 April 2023.

Pre-assignment

Screening details:

A total of 26 subjects were screened and enrolled, of which 5 were screen failure and 21 subjects received the study treatment.

Period 1

Period 1 title	Core Phase (Up to 20 weeks)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel

Arm description:

Subjects of age range from greater than or equal to (>=) 1 month to less than or equal to (<=) 6 months received perampanel 0.5 milligrams (mg), oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 milligram per day (mg/day) (for subjects who are not taking any EIAED]), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 16 weeks (for non-EIAED subjects) and 20 weeks (for EIAED subjects) in Core Phase.

Arm title	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel

Arm description:

Subjects of age range from greater than (>) 6 to <=12 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 16 weeks (for non-EIAED subjects) and 20 weeks (for EIAED subjects) in Core Phase.

Arm title	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel

Arm description:

Subjects of age range from >12 to less than (<) 24 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 16 weeks (for non-EIAED subjects) and 20 weeks (for EIAED subjects) in Core Phase.

Arm title	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel

Arm description:

Subjects of age range from >=24 to <48 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 16 weeks (for non-EIAED subjects) and 20 weeks (for EIAED subjects) in Core Phase.

Number of subjects in period 1	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel
Started	4	5	9
Subjects who did not take EIAED	4	3 [1]	5 [2]
Subjects who took EIAED	0 [3]	2 [4]	4 [5]
Completed	4	5	8
Not completed	0	0	1

Inadequate Therapeutic Effect	-	-	1
Consent withdrawn by subject	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Started	3
Subjects who did not take EIAED	1
Subjects who took EIAED	2
Completed	1
Not completed	2
Inadequate Therapeutic Effect	-
Consent withdrawn by subject	1
Lost to follow-up	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Subjects who did not take EIAED.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Subjects who did not take EIAED.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Subjects who took EIAED.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Subjects who took EIAED.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: .Subjects who took EIAED.

Period 2

Period 2 title	Extension Phase (Up to 36 weeks)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel

Arm description:

Subjects of age range from >=1 month to <=6 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Arm type	Experimental

Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 36 weeks (for non-EIAED subjects) and 32 weeks (for EIAED subjects) after core phase.

Arm title	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel

Arm description:

Subjects of age range from >6 to <=12 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 36 weeks (for non-EIAED subjects) and 32 weeks (for EIAED subjects) after core phase.

Arm title	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel

Arm description:

Subjects of age range from >12 to <24 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Arm type	Experimental
Investigational medicinal product name	Perampanel
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Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 36 weeks (for non-EIAED subjects) and 32 weeks (for EIAED subjects) after core phase.

Arm title	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel

Arm description:

Subjects of age range from >=24 to <48 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Arm type	Experimental
Investigational medicinal product name	Perampanel
Investigational medicinal product code	
Other name	E2007
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received perampanel oral suspension, once daily for up to 36 weeks (for non-EIAED subjects) and 32 weeks (for EIAED subjects) after core phase.

Number of subjects in period 2	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel
Started	4	5	8
Completed	4	5	6
Not completed	0	0	2
Consent withdrawn by subject	-	-	1
Subject choice	-	-	1

Number of subjects in period 2	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Started	1
Completed	1
Not completed	0
Consent withdrawn by subject	-
Subject choice	-

Baseline characteristics

Reporting groups

Reporting group title	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel

Reporting group description:

Subjects of age range from greater than or equal to (>=) 1 month to less than or equal to (<=) 6 months received perampanel 0.5 milligrams (mg), oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 milligram per day (mg/day) (for subjects who are not taking any EIAED]), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group title	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel

Reporting group description:

Subjects of age range from greater than (>) 6 to <=12 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group title	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel

Reporting group description:

Subjects of age range from >12 to less than (<) 24 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group title	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel

Reporting group description:

Subjects of age range from >=24 to <48 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel
Number of subjects	4	5	9
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	4	5	9
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0

Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: months			
arithmetic mean	5.5	10.2	18.8
standard deviation	± 0.58	± 0.84	± 3.73
Sex: Female, Male			
Units: subjects			
Female	2	3	7
Male	2	2	2
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	2
White	3	5	7
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	2
Not Hispanic or Latino	3	5	7
Unknown or Not Reported	0	0	0

Reporting group values	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Total	
Number of subjects	3	21	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	18	
Children (2-11 years)	3	3	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous			
Units: months			
arithmetic mean	31.3		
standard deviation	± 4.16	-	
Sex: Female, Male			
Units: subjects			
Female	1	13	
Male	2	8	

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	2	
White	2	17	
More than one race	1	1	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	4	
Not Hispanic or Latino	2	17	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel

Reporting group description:

Subjects of age range from greater than or equal to (>=) 1 month to less than or equal to (<=) 6 months received perampanel 0.5 milligrams (mg), oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 milligram per day (mg/day) (for subjects who are not taking any EIAED]), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group title	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel

Reporting group description:

Subjects of age range from greater than (>) 6 to <=12 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group title	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel

Reporting group description:

Subjects of age range from >12 to less than (<) 24 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group title	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel

Reporting group description:

Subjects of age range from >=24 to <48 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose up to 12 mg/day (for non-EIAED subjects) or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

Reporting group title	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel

Reporting group description:

Subjects of age range from >=1 month to <=6 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Reporting group title	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel

Reporting group description:

Subjects of age range from >6 to <=12 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Reporting group title	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel

Reporting group description:

Subjects of age range from >12 to <24 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Reporting group title	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel

Reporting group description:

Subjects of age range from >=24 to <48 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Subject analysis set title	Core Phase,Cohort 1,Age>=1 to<=6 Months:Perampanel(Non-EIAED)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of age range from >=1 to <=6 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to 12 mg/day (for subjects who are not taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects.

Subject analysis set title	Core Phase,Cohort 2,Age>6 to<=12 Months:Perampanel(Non-EIAED)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of age range from >6 to <=12 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to 12 mg/day (for subjects who are not taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects.

Subject analysis set title	Core Phase,Cohort 3,Age>12 to<24 Months:Perampanel(Non-EIAED)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of age range from >12 to <24 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to 12 mg/day (for subjects who are not taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects.

Subject analysis set title	Core Phase,Cohort 4,Age>=24 to<48 Months:Perampanel(Non-EIAED)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of age range from >=24 to <48 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to 12 mg/day (for subjects who are not taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects.

Subject analysis set title	Core Phase,Cohort 2,Age>6 to<=12 Months:Perampanel(EIAED)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of age range from >6 to <=12 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment

duration of Core Phase was up to 20 weeks for EIAED subjects.

Subject analysis set title	Core Phase,Cohort 3,Age>12 to<24 Months:Perampanel(EIAED)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of age range from >12 to <24 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 20 weeks for EIAED subjects.

Subject analysis set title	Core Phase,Cohort 4,Age>=24 to<48 Months:Perampanel(EIAED)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of age range from >=24 to <48 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 20 weeks for EIAED subjects.

Primary: Dose Normalized Area Under the Concentration-Time Curve for Dosing Interval at Steady State (AUCtau,ss) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects

End point title	Dose Normalized Area Under the Concentration-Time Curve for Dosing Interval at Steady State (AUCtau,ss) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects[1]

End point description:

Dose normalized AUCtau,ss was calculated as AUCtau,ss/maintenance dose, where AUCtau,ss is area under curve during a dosing interval (tau, 24 hours) at steady state calculated using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated liquid chromatography mass spectrometry (LC MS/MS) analytical method. PK Analysis Set was group of subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. Here, "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 99 and 113: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 99 and 113: Pre-dose, 1-5 hours post-dose (Cohort 4)

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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 1,Age>=1 to<=6 Months:Perampanel(Non-	Core Phase,Cohort 2,Age>6 to<=12 Months:Perampanel(Non-	Core Phase,Cohort 3,Age>12 to<24 Months:Perampanel(Non-	Core Phase,Cohort 4,Age>=24 to<48 Months:Perampanel(Non-
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	4	1
Units: nanogram*hour per milliliter (ng*h/mL)				
arithmetic mean (standard deviation)	3840 (± 2280)	6110 (± 1490)	6030 (± 1940)	5810 (± 99999)

Statistical analyses

No statistical analyses for this end point

Primary: Dose Normalized Maximum (Peak) Steady-state Concentration (Cmax,ss) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects

End point title	Dose Normalized Maximum (Peak) Steady-state Concentration (Cmax,ss) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects[2]

End point description:

Dose normalized Cmax,ss was calculated as Cmax,ss/maintenance dose, where Cmax,ss is the maximum (peak) steady-state concentration calculated using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated LC MS/MS analytical method. PK Analysis Set was group of subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. Here, "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 99 and 113: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 99 and 113: Pre-dose, 1-5 hours post-dose (Cohort 4)

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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 1,Age>=1 to<=6 Months:Perampanel(Non-	Core Phase,Cohort 2,Age>6 to<=12 Months:Perampanel(Non-	Core Phase,Cohort 3,Age>12 to<24 Months:Perampanel(Non-	Core Phase,Cohort 4,Age>=24 to<48 Months:Perampanel(Non-
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	4	1
Units: nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)	305 (± 73.1)	388 (± 68.4)	386 (± 103)	341 (± 99999)

Statistical analyses

No statistical analyses for this end point

Primary: Dose Normalized Average Steady-state Drug Concentration (Css,Av) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects

End point title	Dose Normalized Average Steady-state Drug Concentration (Css,Av) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects[3]

End point description:

Dose normalized Css,Av was calculated as Css,Av/maintenance dose. Css,Av of perampanel was calculated as the ratio of area under the curve (AUC)/tau, (tau = 24 hours for perampanel) using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated LC MS/MS analytical method. PK Analysis Set was group of subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. Here, "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 99 and 113: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 99 and 113: Pre-dose, 1-5 hours post-dose (Cohort 4)

Notes:

[3] - 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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 1,Age>=1 to<=6 Months:Peram panel(Non-	Core Phase,Cohort 2,Age>6 to<=12 Months:Peram panel(Non-	Core Phase,Cohort 3,Age>12 to<24 Months:Peram panel(Non-	Core Phase,Cohort 4,Age>=24 to<48 Months:Peram panel(Non-
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	4	1
Units: ng/mL				
arithmetic mean (standard deviation)	160 (± 95)	255 (± 62.2)	251 (± 80.8)	242 (± 99999)

Statistical analyses

No statistical analyses for this end point

Primary: Dose Normalized Minimum Observed Steady State Plasma Concentration (Cmin,ss) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects

End point title	Dose Normalized Minimum Observed Steady State Plasma Concentration (Cmin,ss) of Perampanel During the Maintenance Period of the Core Phase for Non-EIAED Subjects[4]

End point description:

Dose normalized Cmin,ss was calculated as Cmin,ss/maintenance dose, where Cmin,ss is the minimum observed steady state plasma concentration calculated using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 99 and 113 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated LC MS/MS analytical method. PK Analysis Set was group of subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. Here, "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 99 and 113: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 99 and 113: Pre-dose, 1-5 hours post-dose (Cohort 4)

Notes:

[4] - 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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 1,Age>=1 to<=6 Months:Peram panel(Non-	Core Phase,Cohort 2,Age>6 to<=12 Months:Peram panel(Non-	Core Phase,Cohort 3,Age>12 to<24 Months:Peram panel(Non-	Core Phase,Cohort 4,Age>=24 to<48 Months:Peram panel(Non-
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	4	1
Units: ng/mL				
arithmetic mean (standard deviation)	114 (± 96.4)	203 (± 58.2)	199 (± 71)	203 (± 99999)

Statistical analyses

No statistical analyses for this end point

Primary: Dose Normalized AUCtau,ss of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects

End point title	Dose Normalized AUCtau,ss of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects[5]

End point description:

Dose normalized AUCtau,ss was calculated as AUCtau,ss/maintenance dose, where AUCtau,ss is area under curve during dosing interval (tau, 24 hours) at steady state calculated using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated LC MS/MS analytical method. PK Analysis Set: subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject. No EIAED subject for Cohort 1, hence that arm not reported.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 127 and 141: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 127 and 141: Pre-dose, 1-5 hours post-dose (Cohort 4)

Notes:

[5] - 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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 2,Age>6 to<=12 Months:Peram panel(EIAED)	Core Phase,Cohort 3,Age>12 to<24 Months:Peram panel(EIAED)	Core Phase,Cohort 4,Age>=24 to<48 Months:Peram panel(EIAED)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	3	1	
Units: ng*h/mL				

arithmetic mean (standard deviation)	5220 (± 3600)	3300 (± 1530)	2510 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Primary: Dose Normalized Cmax,ss of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects

End point title	Dose Normalized Cmax,ss of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects[6]

End point description:

Dose normalized Cmax,ss was calculated as Cmax,ss/maintenance dose, where Cmax,ss is the maximum (peak) steady-state concentration calculated using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated LC MS/MS analytical method. PK Analysis Set was group of subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. Here, "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject. No EIAED subject for Cohort 1, hence that arm not reported.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 127 and 141: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 127 and 141: Pre-dose, 1-5 hours post-dose (Cohort 4)

Notes:

[6] - 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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 2,Age>6 to<=12 Months:Peram panel(EIAED)	Core Phase,Cohort 3,Age>12 to<24 Months:Peram panel(EIAED)	Core Phase,Cohort 4,Age>=24 to<48 Months:Peram panel(EIAED)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	3	1	
Units: ng/mL				
arithmetic mean (standard deviation)	341 (± 151)	276 (± 81.8)	201 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Primary: Dose Normalized Css,Av of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects

End point title	Dose Normalized Css,Av of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects[7]

End point description:

Dose normalized Css,Av was calculated as Css,Av/maintenance dose. Css,Av of perampanel was calculated as ratio of area under curve (AUC)/tau, (tau = 24 hours for perampanel) using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated LC MS/MS analytical method. PK Analysis Set: subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject. No EIAED subject for Cohort 1, hence that arm not reported.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 127 and 141: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 127 and 141: Pre-dose, 1-5 hours post-dose (Cohort 4)

Notes:

[7] - 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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 2,Age>6 to<=12 Months:Perampanel(EIAED)	Core Phase,Cohort 3,Age>12 to<24 Months:Perampanel(EIAED)	Core Phase,Cohort 4,Age>=24 to<48 Months:Perampanel(EIAED)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	3	1	
Units: ng/mL				
arithmetic mean (standard deviation)	217 (± 150)	137 (± 63.8)	105 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Primary: Dose Normalized Cmin,ss of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects

End point title	Dose Normalized Cmin,ss of Perampanel During the Maintenance Period of the Core Phase for EIAED Subjects[8]

End point description:

Dose normalized Cmin,ss was calculated as Cmin,ss/maintenance dose, where Cmin,ss is the minimum observed steady state plasma concentration calculated using population PK model. PK sparse sampling was performed. One sample was collected at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 1, Cohort 2, Cohort 3) and two samples were collected, one at pre-dose and other at anytime between 1 to 5 hours post-dose on Days 127 and 141 (Cohort 4). Plasma concentrations of perampanel were measured and concentration data were summarized. Plasma concentrations of perampanel were quantified using a validated LC MS/MS analytical method. PK Analysis Set was group of subjects with at least 1 PK assessment of perampanel during Maintenance Period (Core Phase) with documented dosing history. Here, "Number of Subjects Analyzed" = subjects evaluable for this endpoint and "99999"=data could not be calculated for 1 subject. No EIAED subject for Cohort 1, hence that arm not reported.

End point type	Primary

End point timeframe:

Maintenance Period of the Core Phase- Days 127 and 141: 1-5 hours post-dose (Cohort 1, Cohort 2, Cohort 3); Days 127 and 141: Pre-dose, 1-5 hours post-dose (Cohort 4)

Notes:

[8] - 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: Statistical analyses was not planned for this endpoint.

End point values	Core Phase,Cohort 2,Age>6 to<=12 Months:Perampanel(EIAED)	Core Phase,Cohort 3,Age>12 to<24 Months:Perampanel(EIAED)	Core Phase,Cohort 4,Age>=24 to<48 Months:Perampanel(EIAED)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	3	1	
Units: ng/mL				
arithmetic mean (standard deviation)	172 (± 145)	90.5 (± 53.4)	69.2 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Number of Subjects With Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Core Phase and Extension Phase: Number of Subjects With Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point description:

TEAE: an adverse event (AE) that emerged during treatment, having been absent at pretreatment (Baseline); or re-emerged during treatment, having been present at pretreatment (Baseline) but stopped before treatment; or worsened in severity during treatment relative to the pretreatment state, when AE was continuous. SAE: any untoward medical occurrence that at any dose: Resulted in death; was life-threatening (meaning subject was at an immediate risk of death from AE as it occurred; this did not include an event that, had it occurred in a more severe form or was allowed to continue, might have caused death); Required inpatient hospitalization or prolongation of existing hospitalization; Resulted in persistent or significant disability/incapacity; Was a congenital anomaly/birth defect (in child of a subject who was exposed to the study drug). Safety Analysis Set (SAS) was group of subjects who received at least 1 dose of the study drug and had at least 1 post-dose safety assessment.

End point type	Secondary

End point timeframe:

Core Phase: From the first dose of study drug up to 4 weeks of follow up after the last dose in Core Phase (up to Week 24); Extension Phase: From end of Core Phase treatment up to 4 weeks of follow up after the last dose in Extension Phase (up to Week 56)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: subjects				
Number of Subjects With TEAEs	3	4	5	5
Number of Subjects With SAEs	2	3	1	1

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	3	1
Units: subjects				
Number of Subjects With TEAEs	9	8	3	1
Number of Subjects With SAEs	2	3	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Hematology Laboratory Parameters: Basophils, Eosinophils, Leukocytes, Lymphocytes, Monocytes, Neutrophils, and Platelets

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Hematology Laboratory Parameters: Basophils, Eosinophils, Leukocytes, Lymphocytes, Monocytes, Neutrophils, and Platelets

End point description:

Basophils, eosinophils, leukocytes, lymphocytes, monocytes, neutrophils, and platelets were expressed as 10^9 cells/liter. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameters was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable for specified categories. Here, "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	5
Units: 10^9 cells per liter (/L)				
arithmetic mean (standard deviation)				
Change in Basophils (n= 3, 5, 7, 2, 3, 5, 6, 1)	0.03 (± 0.058)	0.03 (± 0.058)	-0.02 (± 0.110)	0.04 (± 0.219)
Change in Eosinophils (n= 3, 5, 7, 2, 3, 5, 6, 1)	-0.03 (± 0.115)	0.10 (± 0.100)	-0.00 (± 0.100)	0.02 (± 0.148)

Change in Leukocytes (n= 3, 5, 7, 2, 3, 5, 6, 1)	1.73 (± 2.316)	2.43 (± 1.601)	1.26 (± 5.855)	-0.76 (± 4.558)
Change in Lymphocytes (n= 3, 5, 7, 2, 3, 5, 6, 1)	1.00 (± 1.500)	0.53 (± 0.757)	0.62 (± 2.448)	-0.24 (± 1.627)
Change in Monocytes (n= 3, 5, 7, 2, 3, 5, 6, 1)	-0.13 (± 0.153)	0.10 (± 0.100)	0.10 (± 0.308)	-0.10 (± 0.292)
Change in Neutrophils (n= 3, 5, 7, 2, 3, 5, 6, 1)	0.90 (± 0.781)	1.70 (± 0.954)	0.60 (± 3.820)	-0.46 (± 2.518)
Change in Platelets (n= 2, 5, 4, 2, 2, 5, 5, 1)	-44.00 (± 108.894)	7.50 (± 98.288)	-63.80 (± 192.587)	-32.00 (± 280.306)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	2	1
Units: 10^9 cells per liter (/L)				
arithmetic mean (standard deviation)				
Change in Basophils (n= 3, 5, 7, 2, 3, 5, 6, 1)	-0.06 (± 0.151)	-0.05 (± 0.122)	0.00 (± 0.000)	0.00 (± 99999)
Change in Eosinophils (n= 3, 5, 7, 2, 3, 5, 6, 1)	-0.04 (± 0.513)	-0.05 (± 0.399)	-0.15 (± 0.212)	0.00 (± 99999)
Change in Leukocytes (n= 3, 5, 7, 2, 3, 5, 6, 1)	1.10 (± 3.062)	-1.08 (± 4.712)	2.82 (± 6.187)	-1.45 (± 99999)
Change in Lymphocytes (n= 3, 5, 7, 2, 3, 5, 6, 1)	0.54 (± 2.099)	-1.38 (± 2.555)	-1.73 (± 0.813)	-1.75 (± 99999)
Change in Monocytes (n= 3, 5, 7, 2, 3, 5, 6, 1)	0.10 (± 0.606)	-0.02 (± 0.325)	0.33 (± 0.672)	0.25 (± 99999)
Change in Neutrophils (n= 3, 5, 7, 2, 3, 5, 6, 1)	0.51 (± 1.975)	0.38 (± 3.019)	4.35 (± 6.435)	0.10 (± 99999)
Change in Platelets (n= 2, 5, 4, 2, 2, 5, 5, 1)	63.00 (± 167.127)	23.80 (± 147.041)	-22.50 (± 57.276)	-85.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Hematology Laboratory Parameter: Erythrocytes

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Hematology Laboratory Parameter: Erythrocytes

End point description:

Erythrocytes was expressed as 10^12 cells/L. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	5
Units: 10^12 cells/L				
arithmetic mean (standard deviation)	0.44 (± 0.576)	0.27 (± 0.329)	0.16 (± 0.501)	0.39 (± 0.919)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	2	1
Units: 10^12 cells/L				
arithmetic mean (standard deviation)	0.10 (± 0.155)	-0.14 (± 0.396)	-0.10 (± 0.283)	-0.03 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Hematology Laboratory Parameter: Hemoglobin

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Hematology Laboratory Parameter: Hemoglobin

End point description:

Hemoglobin was expressed as grams per liter (g/L). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	5
Units: g/L				
arithmetic mean (standard deviation)	14.00 (± 18.000)	10.00 (± 8.888)	5.20 (± 8.899)	12.80 (± 20.945)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	2	1
Units: g/L				
arithmetic mean (standard deviation)	3.14 (± 3.237)	-1.33 (± 13.808)	-0.25 (± 3.889)	-6.50 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Alanine Aminotransferase, Alkaline Phosphatase, Aspartate Aminotransferase, Gamma Glutamyl Transferase, Lactate Dehydrogenase

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Alanine Aminotransferase, Alkaline Phosphatase, Aspartate Aminotransferase, Gamma Glutamyl Transferase, Lactate Dehydrogenase

End point description:

Alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, gamma glutamyl transferase, lactate dehydrogenase were expressed as units per liter (U/L). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameters was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: U/L				
arithmetic mean (standard deviation)				
Change in Alanine Aminotransferase	-2.25 (± 7.932)	36.50 (± 90.820)	-16.00 (± 27.803)	-16.00 (± 27.313)
Change in Alkaline Phosphatase	43.50 (± 115.610)	-12.75 (± 97.072)	266.00 (± 652.320)	-32.40 (± 147.179)
Change in Aspartate Aminotransferase	-2.00 (± 2.449)	21.00 (± 58.980)	-12.20 (± 21.993)	-13.20 (± 22.477)
Change in Gamma Glutamyl Transferase	12.50 (± 87.577)	50.00 (± 320.278)	-3.00 (± 3.536)	-5.40 (± 4.336)
Change in Lactate Dehydrogenase	-6.00 (± 50.721)	1.00 (± 68.775)	-32.60 (± 54.574)	-44.60 (± 49.863)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	2	1
Units: U/L				
arithmetic mean (standard deviation)				
Change in Alanine Aminotransferase	-13.71 (± 33.265)	-11.43 (± 37.228)	6.00 (± 15.556)	-4.00 (± 99999)
Change in Alkaline Phosphatase	23.86 (± 21.162)	-77.29 (± 205.368)	-46.50 (± 53.033)	-58.00 (± 99999)
Change in Aspartate Aminotransferase	-6.57 (± 16.009)	-8.43 (± 19.569)	0.50 (± 3.536)	1.00 (± 99999)
Change in Gamma Glutamyl Transferase	-15.71 (± 31.653)	-23.71 (± 48.801)	5.00 (± 5.657)	-1.00 (± 99999)
Change in Lactate Dehydrogenase	-14.43 (± 28.425)	-17.29 (± 67.037)	51.50 (± 132.229)	-39.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameter: Bilirubin

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameter: Bilirubin

End point description:

Bilirubin was expressed as micromoles per liter (mcmol/L). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as

1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: mcmol/L				
arithmetic mean (standard deviation)	-0.30 (± 0.600)	-0.10 (± 0.200)	0.64 (± 2.057)	1.24 (± 2.414)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	2	1
Units: mcmol/L				
arithmetic mean (standard deviation)	-0.46 (± 1.555)	-0.57 (± 1.093)	0.70 (± 0.990)	0.90 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Calcium, Chloride, Cholesterol, Glucose, Phosphate, Potassium, Sodium, Triglycerides, Urea Nitrogen

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Calcium, Chloride, Cholesterol, Glucose, Phosphate, Potassium, Sodium, Triglycerides, Urea Nitrogen

End point description:

Calcium, chloride, cholesterol, glucose, phosphate, potassium, sodium, triglycerides, urea nitrogen were expressed as millimoles per liter (mmol/L). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameters was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable for specified categories. Here, "99999" signifies data could not be calculated due insufficient or no subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: mmol/L				
arithmetic mean (standard deviation)				
Change in Calcium (n=4,5,7,2,4,5,7,1)	-0.08 (± 0.147)	-0.05 (± 0.123)	0.02 (± 0.095)	0.05 (± 0.139)
Change in Chloride (n=4,5,7,2,4,5,7,1)	-0.25 (± 2.500)	0.00 (± 2.160)	-0.80 (± 1.304)	-2.60 (± 3.578)
Change in Cholesterol (n=4,5,7,2,4,5,7,1)	0.45 (± 0.191)	-0.55 (± 0.583)	0.52 (± 1.102)	1.48 (± 1.369)
Change in Glucose (n=2,4,2,0,2,4,5,0)	-0.42 (± 0.898)	0.34 (± 1.096)	0.78 (± 0.668)	0.18 (± 0.249)
Change in Phosphate (n=4,2,7,2,4,2,7,1)	-0.22 (± 0.277)	0.05 (± 0.169)	0.11 (± 0.339)	0.16 (± 0.042)
Change in Potassium (n=4,5,7,2,4,5,7,1)	-0.23 (± 0.222)	-0.10 (± 0.712)	0.06 (± 0.167)	-0.02 (± 0.669)
Change in Sodium (n=4,5,7,2,4,5,7,1)	1.25 (± 2.986)	0.50 (± 3.109)	0.00 (± 2.236)	-0.40 (± 2.408)
Change in Triglycerides (n=4,5,7,2,4,5,7,1)	0.94 (± 0.619)	0.54 (± 0.602)	-0.50 (± 0.641)	-0.05 (± 0.910)
Change in Urea Nitrogen (n=4,5,7,2,4,5,7,1)	0.27 (± 0.791)	1.69 (± 0.942)	0.74 (± 1.440)	0.89 (± 3.316)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	2	1
Units: mmol/L				
arithmetic mean (standard deviation)				
Change in Calcium (n=4,5,7,2,4,5,7,1)	-0.00 (± 0.098)	-0.02 (± 0.103)	-0.01 (± 0.014)	-0.04 (± 99999)
Change in Chloride (n=4,5,7,2,4,5,7,1)	-1.71 (± 3.450)	0.43 (± 1.988)	-1.00 (± 2.828)	1.00 (± 99999)
Change in Cholesterol (n=4,5,7,2,4,5,7,1)	-0.02 (± 0.505)	0.19 (± 0.578)	0.58 (± 0.311)	0.83 (± 99999)
Change in Glucose (n=2,4,2,0,2,4,5,0)	-0.24 (± 1.450)	-0.07 (± 0.640)	99999 (± 99999)	99999 (± 99999)
Change in Phosphate (n=4,2,7,2,4,2,7,1)	-0.00 (± 0.154)	-0.08 (± 0.145)	-0.31 (± 0.714)	0.07 (± 99999)
Change in Potassium (n=4,5,7,2,4,5,7,1)	0.19 (± 0.652)	0.21 (± 0.285)	0.25 (± 0.212)	-0.60 (± 99999)

Change in Sodium (n=4,5,7,2,4,5,7,1)	-1.86 (± 2.911)	1.14 (± 0.690)	4.00 (± 4.243)	-2.00 (± 99999)
Change in Triglycerides (n=4,5,7,2,4,5,7,1)	0.27 (± 1.047)	-0.09 (± 0.544)	0.44 (± 0.156)	0.05 (± 99999)
Change in Urea Nitrogen (n=4,5,7,2,4,5,7,1)	-0.97 (± 1.296)	0.61 (± 1.694)	0.18 (± 1.768)	0.36 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Creatinine, Direct Bilirubin, Urate

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Creatinine, Direct Bilirubin, Urate

End point description:

Creatinine, direct bilirubin, urate were expressed as micromoles per liter (mcmol/L). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameters was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: mcmol/L				
arithmetic mean (standard deviation)				
Change in Creatinine	2.25 (± 4.505)	6.51 (± 8.187)	1.80 (± 4.024)	3.61 (± 4.929)
Change in Direct Bilirubin	0.00 (± 0.000)	0.00 (± 0.000)	0.08 (± 0.183)	0.08 (± 0.183)
Change in Urate	0.00 (± 0.024)	-0.01 (± 0.054)	-0.02 (± 0.064)	0.01 (± 0.086)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	2	1
Units: mcmol/L				

arithmetic mean (standard deviation)				
Change in Creatinine	-1.28 (± 3.402)	1.29 (± 3.400)	4.51 (± 6.357)	9.00 (± 99999)
Change in Direct Bilirubin	0.00 (± 0.000)	0.00 (± 0.000)	0.00 (± 0.000)	0.00 (± 99999)
Change in Urate	-0.02 (± 0.032)	-0.00 (± 0.045)	0.01 (± 0.097)	0.04 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Albumin, Globulin, Protein

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Clinical Chemistry Laboratory Parameters: Albumin, Globulin, Protein

End point description:

Albumin, globulin, protein were expressed as g/L. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameters was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: g/L				
arithmetic mean (standard deviation)				
Change in Albumin	0.50 (± 1.291)	2.00 (± 3.266)	2.00 (± 4.183)	5.60 (± 7.335)
Change in Globulin	2.50 (± 6.455)	7.25 (± 8.057)	-2.20 (± 3.114)	0.20 (± 3.347)
Change in Protein	3.00 (± 5.657)	9.25 (± 9.287)	-0.20 (± 2.588)	5.80 (± 7.596)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	2	1

Units: g/L				
arithmetic mean (standard deviation)				
Change in Albumin	-0.29 (± 2.059)	-0.29 (± 2.870)	-1.00 (± 4.243)	2.00 (± 99999)
Change in Globulin	0.71 (± 1.496)	3.43 (± 2.760)	-2.00 (± 2.828)	3.00 (± 99999)
Change in Protein	0.43 (± 3.047)	3.14 (± 3.934)	-3.00 (± 7.071)	5.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameters: Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameters: Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

End point description:

SBP and DBP were measured after the subject sitting or supine, for 5 minutes. SBP and DBP were expressed as millimeter of mercury (mmHg). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameters was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable for specified categories. Here, "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	5
Units: mmHg				
arithmetic mean (standard deviation)				
Change in SBP (n= 3, 5, 9, 3, 2, 5, 6, 1)	-1.00 (± 26.211)	25.00 (± 42.426)	0.60 (± 6.066)	4.00 (± 5.477)
Change in DBP (n= 3, 5, 9, 3, 3, 5, 8, 1)	-5.33 (± 3.786)	23.00 (± 20.298)	4.40 (± 5.857)	1.60 (± 5.941)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	3	1
Units: mmHg				
arithmetic mean (standard deviation)				
Change in SBP (n= 3, 5, 9, 3, 2, 5, 6, 1)	0.33 (± 19.780)	12.00 (± 20.040)	10.33 (± 4.726)	16.00 (± 99999)
Change in DBP (n= 3, 5, 9, 3, 3, 5, 8, 1)	-0.89 (± 10.659)	6.00 (± 9.885)	8.67 (± 6.429)	0.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameter: Pulse Rate

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameter: Pulse Rate

End point description:

Pulse rate measured after the subject sitting or supine, for 5 minutes and was expressed in beats per minute (beats/min). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: beats/min				
arithmetic mean (standard deviation)	5.25 (± 16.112)	-9.25 (± 14.773)	-4.40 (± 7.537)	-15.80 (± 11.670)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	3	1
Units: beats/min				
arithmetic mean (standard deviation)	-14.89 (±	-13.75 (±	-21.67 (±	-26.00 (±

	14.675)	9.543)	21.127)	99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameter: Respiratory Rate

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameter: Respiratory Rate

End point description:

Respiratory rate was the number of breaths taken per minute, measured at rest. Respiratory rate was expressed as breaths per minute (breaths/min). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	5
Units: breaths/min				
arithmetic mean (standard deviation)	-5.33 (± 6.110)	-4.33 (± 7.506)	-3.00 (± 4.183)	-4.80 (± 5.541)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	3	1
Units: breaths/min				
arithmetic mean (standard deviation)	-4.78 (± 8.243)	-3.88 (± 7.415)	-5.33 (± 2.309)	6.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameter: Body Temperature

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Vital Sign Parameter: Body Temperature

End point description:

Body temperature was expressed as degree centigrade. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	5
Units: degree centigrade				
arithmetic mean (standard deviation)	0.10 (± 0.265)	0.47 (± 0.702)	-0.02 (± 0.130)	0.02 (± 0.045)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	3	1
Units: degree centigrade				
arithmetic mean (standard deviation)	0.02 (± 0.199)	-0.16 (± 0.311)	0.13 (± 0.153)	-0.20 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Weight

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Weight

End point description:

Weight was expressed as kilograms. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: kilograms				
arithmetic mean (standard deviation)	1.88 (± 0.377)	3.88 (± 2.081)	1.20 (± 1.065)	3.24 (± 1.356)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	3	1
Units: kilograms				
arithmetic mean (standard deviation)	1.01 (± 1.134)	2.88 (± 1.792)	0.77 (± 0.153)	0.90 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Height

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Height

End point description:

Height was expressed as centimeters. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose

safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: centimeters				
arithmetic mean (standard deviation)	4.76 (± 2.197)	17.65 (± 3.643)	5.20 (± 2.361)	12.78 (± 2.548)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	2	1
Units: centimeters				
arithmetic mean (standard deviation)	5.06 (± 1.429)	10.24 (± 1.849)	3.63 (± 1.237)	6.50 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Head Circumference

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Head Circumference

End point description:

Head circumference was expressed as centimeters. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: centimeters				
arithmetic mean (standard deviation)	1.87 (± 1.231)	4.02 (± 0.846)	1.50 (± 1.061)	2.50 (± 0.791)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	2	1
Units: centimeters				
arithmetic mean (standard deviation)	1.14 (± 1.927)	2.36 (± 1.537)	-0.15 (± 0.495)	0.50 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core and Extension Phase: Mean Change from Baseline in ECG Parameters: Single Beat Heart rate-corrected QT Interval (QTcB), QT Interval Corrected According to the Formula of Fridericia (QTcF), PR and QT Intervals, QRS Duration, and Aggregate RR Interval

End point title	Core and Extension Phase: Mean Change from Baseline in ECG Parameters: Single Beat Heart rate-corrected QT Interval (QTcB), QT Interval Corrected According to the Formula of Fridericia (QTcF), PR and QT Intervals, QRS Duration, and Aggregate RR Interval

End point description:

QTc: time from beginning of QRS complex to end of T wave, corrected for heart rate. QT interval: time from ECG Q wave to end of T wave corresponding to electrical systole. QRS interval: time from ECG Q wave to end of S wave, corresponding to ventricle depolarization. PR interval: time between beginning of P wave and start of QRS interval, corresponding to end of atrial depolarization and onset of ventricular depolarization. RR interval: time elapsed between two successive R waves of QRS signal. Single beat QTcB, QTcF, PR and QT Interval, QRS duration and aggregate RR interval were expressed as millisecond (msec). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. SAS: subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed"=subjects evaluable for this endpoint and "n"= subjects evaluable for specified categories. "99999"= data could not be calculated for 1 subject.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: msec				
arithmetic mean (standard deviation)				
Single Beat QTcB Interval (n=4,5,8,3,4,5,6,1)	-9.0 (± 24.06)	-29.75 (± 27.476)	-7.0 (± 26.29)	-5.60 (± 32.168)
Single Beat QTcF Interval (n=4,5,8,3,4,5,6,1)	-4.5 (± 20.86)	-8.25 (± 22.721)	-10.0 (± 21.99)	-2.40 (± 36.115)
Single Beat PR Interval (n=4,5,8,3,4,5,6,1)	-2.8 (± 4.57)	3.00 (± 3.162)	-2.8 (± 8.47)	3.80 (± 13.236)
Single Beat QRS Duration (n=4,5,8,3,4,5,6,1)	-0.5 (± 5.45)	3.75 (± 2.986)	-0.2 (± 5.89)	-1.20 (± 6.181)
Aggregate RR Interval (n=4,5,9,3,4,5,7,1)	28.3 (± 35.36)	165.25 (± 31.127)	-30.4 (± 26.37)	23.00 (± 72.087)
Single Beat QT Interval (n=4,5,8,3,4,5,6,1)	1.8 (± 17.23)	23.25 (± 14.569)	-13.8 (± 16.04)	2.40 (± 41.374)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	3	1
Units: msec				
arithmetic mean (standard deviation)				
Single Beat QTcB Interval (n=4,5,8,3,4,5,6,1)	-3.8 (± 33.86)	4.33 (± 8.710)	17.0 (± 14.42)	58.00 (± 99999)
Single Beat QTcF Interval (n=4,5,8,3,4,5,6,1)	1.9 (± 29.95)	1.17 (± 9.347)	5.7 (± 8.62)	27.00 (± 99999)
Single Beat PR Interval (n=4,5,8,3,4,5,6,1)	-1.1 (± 16.66)	2.50 (± 8.689)	-10.3 (± 12.66)	-3.00 (± 99999)
Single Beat QRS Duration (n=4,5,8,3,4,5,6,1)	-0.8 (± 3.20)	-1.67 (± 3.830)	-6.0 (± 8.00)	1.00 (± 99999)
Aggregate RR Interval (n=4,5,9,3,4,5,7,1)	60.7 (± 61.84)	20.57 (± 81.506)	-76.7 (± 77.36)	-178.00 (± 99999)
Single Beat QT Interval (n=4,5,8,3,4,5,6,1)	10.6 (± 29.61)	-3.17 (± 15.779)	-10.0 (± 18.33)	-16.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in ECG

Parameter: ECG Ventricular Rate

End point title	Core Phase and Extension Phase: Mean Change from Baseline in ECG Parameter: ECG Ventricular Rate

End point description:

Ventricular rate is determined by dividing 60 by the mean RR interval of the ECG in seconds (mean time between QRS complexes) to get beats per minute. ECG ventricular rate was expressed as beats/min. Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: beats/min				
arithmetic mean (standard deviation)	-7.5 (± 9.04)	-36.25 (± 4.272)	8.6 (± 7.37)	-4.40 (± 15.437)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	3	1
Units: beats/min				
arithmetic mean (standard deviation)	-12.2 (± 11.39)	-3.14 (± 17.837)	18.7 (± 22.85)	50.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Thyroid Stimulating Hormone (TSH): Thyrotropin

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Thyroid Stimulating Hormone (TSH): Thyrotropin

End point description:

Thyrotropin was expressed as milli-international units per liter (mIU/L). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of

study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	3	5
Units: mIU/L				
arithmetic mean (standard deviation)	1.12 (± 1.242)	0.05 (± 0.590)	-1.02 (± 0.279)	-0.89 (± 1.405)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	1	1
Units: mIU/L				
arithmetic mean (standard deviation)	1.33 (± 1.283)	-0.08 (± 1.026)	-0.90 (± 99999)	-0.35 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change From Baseline in Insulin-like Growth Factor 1 (IGF-1)

End point title	Core Phase and Extension Phase: Mean Change From Baseline in Insulin-like Growth Factor 1 (IGF-1)

End point description:

IGF-1 was expressed as millimoles per liter*10^-6 (mmol/L*10^-6). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameter was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	3	4
Units: mmol/L*10^-6				
arithmetic mean (standard deviation)	-2.00 (± 99999)	6.00 (± 0.000)	7.00 (± 3.606)	4.75 (± 5.439)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	1	1
Units: mmol/L*10^-6				
arithmetic mean (standard deviation)	3.60 (± 6.066)	6.29 (± 9.160)	1.00 (± 99999)	-1.00 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Core Phase and Extension Phase: Mean Change from Baseline in Free Thyroxine, and Free Triiodothyronine

End point title	Core Phase and Extension Phase: Mean Change from Baseline in Free Thyroxine, and Free Triiodothyronine

End point description:

Free thyroxine, and free triiodothyronine were expressed as picomoles per liter (pmol/L). Change from Baseline was calculated as post-Baseline absolute value minus Baseline value. Mean change from baseline data for specified parameters was reported. The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "99999" signifies standard deviation could not be calculated as 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Core Phase: Baseline, end of Core Phase treatment (up to Week 20); Extension Phase: Baseline (Core Phase), end of Extension Phase treatment (Week 52)

End point values	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	1	3
Units: pmol/L				
arithmetic mean (standard deviation)				
Change in Free Thyroxine	0.90 (± 1.931)	2.55 (± 1.021)	-1.30 (± 99999)	0.83 (± 1.443)
Change in Free Triiodothyronine	-0.40 (± 0.889)	0.28 (± 1.250)	0.60 (± 99999)	1.03 (± 0.611)

End point values	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	1	1
Units: pmol/L				
arithmetic mean (standard deviation)				
Change in Free Thyroxine	-1.80 (± 1.147)	0.00 (± 0.919)	-3.90 (± 99999)	-3.90 (± 99999)
Change in Free Triiodothyronine	0.06 (± 0.885)	-0.16 (± 1.230)	-4.30 (± 99999)	-1.80 (± 99999)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Core Phase: From the first dose of study drug up to 4 weeks of follow up after the last dose in Core Phase (up to Week 24); Extension Phase: From end of Core Phase treatment up to 4 weeks of follow up after the last dose in Extension Phase (up to Week 56)

Adverse event reporting additional description:

The SAS was the group of subjects who received at least 1 dose of study drug and had at least 1 post-dose safety assessment.

| Assessment type | Systematic |

Dictionary used

| Dictionary name | MedDRA |
| Dictionary version | 25.1 |

Reporting groups

| Reporting group title | Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel |

Reporting group description:

Subjects of age range from >=1 month to <=6 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

| Reporting group title | Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel |

Reporting group description:

Subjects of age range from >6 to <=12 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

| Reporting group title | Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel |

Reporting group description:

Subjects of age range from >12 to <24 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

| Reporting group title | Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel |

Reporting group description:

Subjects of age range from >=24 to <48 months received perampanel 0.5 mg, oral suspension, before bedtime during Week 0 and then dose up titrated to a maximum of 12 mg/day (for subjects who are not taking any EIAED), or titrated up to a maximum of 16 mg/day (for subjects who are taking any EIAED). Dose titration was up to Week 12 for Non-EIAED subjects and up to Week 16 for EIAED subjects to identify each subject's optimum dose during Core Phase. Subjects then continued to take perampanel at optimal dose level 12 mg/day (for Non-EIAED subjects or 16 mg/day (for EIAED subjects) as a maintenance dose for up to 4 weeks during Core Phase. The total treatment duration of Core Phase was up to 16 weeks for non-EIAED subjects or up to 20 weeks for EIAED subjects.

| Reporting group title | Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel |

Reporting group description:

Subjects of age range from >=1 month to <=6 months who completed the Core Phase continued their

optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Reporting group title	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel

Reporting group description:

Subjects of age range from >6 to <=12 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Reporting group title	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel

Reporting group description:

Subjects of age range from >12 to <24 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Reporting group title	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel

Reporting group description:

Subjects of age range from >=24 to <48 months who completed the Core Phase continued their optimal perampanel oral suspension, at the dose level achieved at the end of the Treatment Phase. The maximum total daily allowed dose for a non-EIAED subject was 12 mg and 16 mg for EIAED subjects. The total treatment duration of Extension Phase was up to 36 weeks for non-EIAED subjects and 32 weeks for EIAED subjects.

Serious adverse events	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	1 / 5 (20.00%)	2 / 9 (22.22%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			

subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders

Aspiration

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders

Mental Status Changes

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations

Bullous impetigo

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Upper respiratory tract infection

subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rhinovirus infection

subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory Syncytial Virus Infection

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure To Thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	3 / 4 (75.00%)	1 / 5 (20.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental Status Changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bullous impetigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure To Thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders

Aspiration

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Psychiatric disorders

Mental Status Changes

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Infections and infestations

Bullous impetigo

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Upper respiratory tract infection

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Rhinovirus infection

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Pneumonia

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Respiratory Syncytial Virus Infection

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Influenza		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenovirus Infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parainfluenzae Virus Infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovirus Infection		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Covid-19		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Aspiration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Bacterial		

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Failure To Thrive			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 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	Core Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Core Phase, Cohort 2, Age >6 to <=12 Months: Perampanel	Core Phase, Cohort 3, Age >12 to <24 Months: Perampanel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	5 / 5 (100.00%)	9 / 9 (100.00%)
Investigations			
Oxygen Saturation Decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gamma-Glutamyltransferase Increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications

Lip Injury

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Skin Laceration

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders

Somnolence

subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	2 / 9 (22.22%)
occurrences (all)	0	2	3

Seizure

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 9 (11.11%)
occurrences (all)	0	2	1

Balance Disorder

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Ataxia

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	1

Status Epilepticus

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions

Pyrexia

subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	5 / 9 (55.56%)
occurrences (all)	1	0	9

Hypothermia

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders

Ear Pain

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	2 / 9 (22.22%)
occurrences (all)	0	1	3
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	3 / 9 (33.33%)
occurrences (all)	0	1	5
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Irritability			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Sinusitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	3 / 5 (60.00%)	3 / 9 (33.33%)
occurrences (all)	0	4	4
Rhinitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	3 / 9 (33.33%)
occurrences (all)	1	0	3
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	8
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia Aspiration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rotavirus Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device Dislocation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Failure To Thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Malnutrition			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Core Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	Extension Phase, Cohort 1, Age >=1 to <=6 Months: Perampanel	Extension Phase, Cohort 2, Age >6 to <=12 Months: Perampanel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	5 / 5 (100.00%)
Investigations			
Oxygen Saturation Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Lip Injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Skin Laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seizure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Balance Disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Status Epilepticus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Hypothermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Faecaloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nasal Congestion			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	2	0	4
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Rotavirus Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device Dislocation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Failure To Thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Extension Phase, Cohort 3, Age >12 to <24 Months: Perampanel	Extension Phase, Cohort 4, Age >=24 to <48 Months: Perampanel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	1 / 1 (100.00%)	
Investigations			
Oxygen Saturation Decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Alanine Aminotransferase Increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Aspartate Aminotransferase Increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Gamma-Glutamyltransferase Increased		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Injury, poisoning and procedural complications		
Lip Injury		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Skin Laceration		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Nervous system disorders		
Somnolence		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	2	0
Seizure		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Balance Disorder		
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	1
Ataxia		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Status Epilepticus		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	2	0
General disorders and administration site conditions		
Pyrexia		

subjects affected / exposed	3 / 8 (37.50%)	1 / 1 (100.00%)	
occurrences (all)	3	2	
Hypothermia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	1 / 1 (100.00%)	
occurrences (all)	2	1	
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Dyspepsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Faecaloma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Teething			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Asthma		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Cough		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Nasal Congestion		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Psychiatric disorders		
Aggression		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Irritability		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Insomnia		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Infections and infestations		
Sinusitis		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Nasopharyngitis		
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)
occurrences (all)	2	0
Rhinitis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Upper Respiratory Tract Infection		
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)
occurrences (all)	3	0
Gastroenteritis		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Ear Infection		

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

Cellulitis

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	2	0

Bronchitis

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

Gastroenteritis Viral

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

Influenza

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

Pharyngitis Streptococcal

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

Pneumonia

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

Pneumonia Aspiration

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0

Rotavirus Infection

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0

Viral Upper Respiratory Tract Infection

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

Product issues
  Device Dislocation

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0

Metabolism and nutrition disorders

Decreased Appetite		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Dehydration		
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0
Failure To Thrive		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Malnutrition		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0
Vitamin D Deficiency		
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)
occurrences (all)	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 February 2017	Amendment 01: Changed the gestational age from 41 to 36 weeks in inclusion criterion 1; Removed 4-week time frame of last seizure occurrence prior to Visit 1 from inclusion criterion 5; Changed seizure surgery restriction from "before Visit 1" to "within 1 year of Visit 1" in exclusion criterion 4.
09 April 2020	Amendment 2: For non-EIAED subjects, target perampanel dose was lowered to 4 mg/day. Depending upon individual clinical response and tolerability, non-EIAED subjects could still have their perampanel dose up-titrated to 6 mg/day. Added a cohort of subjects from 2 to less than 4 years of age and specified total number of subjects required when pooled across multiple studies; Made editorial changes to study endpoints; Increased overall study duration; Deleted Clinical Global Impression of Severity (CGI-S) from exploratory objectives and endpoints; Increased the allowed number of concomitant anti-epileptic drugs (AEDs) from 3 to 4; Lowered the target dose to 6 mg/day for non-enzyme-inducing anti-epileptic drug (non-EIAED) and to 8 mg/day for EIAED subjects; Specified conditions for further up-titrations to maximum allowed doses up to 12 mg/day for non-EIAED and 16 mg/day for EIAED subjects; Modified the period during which concomitant AED doses must have remained stable for eligibility determination; Modified the period during which concomitant central nervous system (CNS) drugs must have remained stable, and specified that these drugs are prohibited throughout the course of the study; Modified exclusion criterion related to prior or concomitant use of felbamate and vigabatrin and specified that these drugs are prohibited throughout the course of the study.
09 April 2020	Amendment 02 (continued): Modified the exclusion criterion related to prior use of perampanel; Specified that concomitant use of cannabidiol (CBD) products is allowed; Modified concomitant therapy section to allow dose adjustments of concomitant AEDs (non-enzyme inducing AEDs only) during the Core study. AED addition or deletion will remain prohibited during the Core Study; Specified that the subjects who immediately switch to commercially available perampanel after the last dose of study drug at the end of Core Study or Extension Phase need not undergo Follow-up Period/Visit; Added description of sample size calculations for the 2 to less than 4 years of age group; Lipid and blood glucose tests are to be collected under fasting conditions, whenever practically feasible, at all-time points; Clarified baseline seizure frequency data for efficacy endpoint analyses; Added early PK sampling time points at predose and 1 to 5 hours postdose for subjects of 2 to less than 4 years of age and adjusted dosing instructions around PK visits during Maintenance Period. Added a statement that the dose-normalized derived exposure parameters will be summarized for age groups.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

 None reported