Long-Term Safety, Tolerability and Efficacy in Perampanel Treated Parkinson's Disease Patients With Motor Fluctuations

This study has been terminated.

(Due to termination of clinical program for Parkinson's Disease)

Sponsor:
Eisai Inc.

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT01634360

First received: July 3, 2012
Last updated: June 25, 2014
Last verified: January 2013
History of Changes

Results First Received: October 23, 2012

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Parkinson's Disease
Intervention:	Drug: Perampanel

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-E044-204). Subjects started on perampanel 1mg once daily for 4 weeks, followed by 2mg once daily for 2 weeks; if they did not tolerate the 1 mg dose, subjects were withdrawn from the study. Subjects could be up-titrated to 3 or 4

	mg in a sequential manner. There were at least 2 weeks between each titration to assess safety and tolerability, and the subjects attended a clinic visit for safety review and dispensing of more medication. Subjects could be down-titrated at any time to either 3, 2 or 1 mg in a sequential manner.
Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-E044-204). Subjects started on perampanel 1mg once daily for 4 weeks, followed by 2mg once daily for 2 weeks; if they did not tolerate the 1 mg dose, subjects were withdrawn from the study. Subjects could be up-titrated to 3 or 4 mg in a sequential manner. There were at least 2 weeks between each titration to assess safety and tolerability, and the subjects attended a clinic visit for safety review and dispensing of more medication. Subjects could be down-titrated at any time to either 3, 2 or 1 mg in a sequential manner.

Participant Flow: Overall Study

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)
STARTED	**49**	**136**
COMPLETED	**0**	**0**
NOT COMPLETED	**49**	**136**
Adverse Event	**10**	**34**
subject withdrew consent	**13**	**23**
Protocol Violation	**1**	**1**
Lack of Efficacy	**4**	**14**
Not specified	**3**	**20**
Study termination by sponsor	**18**	**44**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
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Total	Total of all reporting groups

Baseline Measures

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)	Total
Overall Participants Analyzed [Units: Participants]	**48**	**134**	**182**
Age, Customized [1] [Units: Participants]			
<65 years	**27**	**72**	**99**
>=65 years	**21**	**62**	**83**
[1] Safety population			
Gender [1] [Units: Participants]			
Female	**23**	**54**	**77**
Male	**25**	**80**	**105**
[1] The participant flow information was collected from all participants who entered the study. Baseline information was collected only for the safety population (all subjects who received at least 1 dose of perampanel in this study and at least 1 dose of study medication during the double-blind phase of the core study).			
Race/Ethnicity, Customized [1] [Units: Participants]			
Caucasian	**48**	**134**	**182**
[1] Race			

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study [Time Frame: Baseline, Week 0, Week 12, Week 24, Week 36, Week 52, Week 78, Week 104, Week 130, Week 156]

Measure Type	Primary
Measure Title	Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study
Measure Description	OFF state is when medication has worn off and is no longer providing benefits with regard to stiffness, slowness, and tremor. This outcome measure was based on data collected through use of a patient diary.
Time Frame	Baseline, Week 0, Week 12, Week 24, Week 36, Week 52, Week 78, Week 104, Week 130, Week 156
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy Population- All subjects who were in the Safety Population and for whom at least 1 postbaseline (post Week 0) efficacy assessment was made.

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-E044-204). Subjects started on perampanel 1mg once daily for 4 weeks, followed by 2mg once daily for 2 weeks; if they did not tolerate the 1 mg dose, subjects were withdrawn from the study. Subjects could be up-titrated to 3 or 4 mg in a sequential manner. There were at least 2 weeks between each titration to assess safety and tolerability, and the subjects attended a clinic visit for safety review and dispensing of more medication. Subjects could be down-titrated at any time to either 3, 2 or 1 mg in a sequential manner.
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Measured Values

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)
Participants Analyzed [Units: Participants]	**45**	**125**
Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study [Units: Hours] Mean (Standard Deviation)		
Week 0	**-0.51 (2.811)**	**-0.68 (2.479)**
Week 12	**-0.91 (2.913)**	**-1.08 (2.907)**
Week 24	**-1.05 (2.760)**	**-1.15 (2.754)**
Week 36	**-0.76 (2.638)**	**-1.16 (2.959)**
Week 52	**-0.47 (3.443)**	**-1.34 (2.881)**
Week 78	**-1.31 (2.547)**	**-1.54 (3.106)**
Week 104	**-1.14 (3.121)**	**-1.81 (3.149)**
Week 130	**-0.65 (3.710)**	**-1.62 (2.953)**
Week 156	**-1.00 (2.953)**	**-1.16 (2.672)**

No statistical analysis provided for Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study

2. Secondary: Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study [Time Frame: Baseline, Week 0, Week 12, Week 24, Week 36, Week 52, Week 78, Week 104, Week 130, Week 156]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study
Measure Description	ON state is when medication is providing benefits with regard to stiffness, slowness, and tremor. This outcome measure was based on data collected through use of a patient diary.

Time Frame	Baseline, Week 0, Week 12, Week 24, Week 36, Week 52, Week 78, Week 104, Week 130, Week 156
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy Population

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-E044-204). Subjects started on perampanel 1mg once daily for 4 weeks, followed by 2mg once daily for 2 weeks; if they did not tolerate the 1 mg dose, subjects were withdrawn from the study. Subjects could be up-titrated to 3 or 4 mg in a sequential manner. There were at least 2 weeks between each titration to assess safety and tolerability, and the subjects attended a clinic visit for safety review and dispensing of more medication. Subjects could be down-titrated at any time to either 3, 2 or 1 mg in a sequential manner.
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Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)**
Participants Analyzed [Units: Participants]	**45**	**125**
Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study [Units: Hours] Mean (Standard Deviation)		
Week 0	**0.85 (2.856)**	**1.17 (3.562)**
Week 12	**1.47 (3.200)**	**1.32 (3.758)**
Week 24	**1.89 (3.712)**	**0.86 (3.632)**
Week 36	**1.40 (3.895)**	**1.52 (4.153)**
Week 52	**0.81 (4.101)**	**1.79 (4.238)**
Week 78	**1.39 (4.450)**	**2.52 (4.625)**
Week 104	**0.21 (4.541)**	**3.30 (4.617)**
Week 130	**-0.98 (4.276)**	**1.42 (4.013)**
Week 156	**-0.73 (4.105)**	**1.76 (4.974)**

No statistical analysis provided for Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study

3. Secondary: Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study [Time

Frame: Baseline, Week 0, Week 12, Week 24, Week 36, Week 52, Week 78, Week 104, Week 130, Week 156]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study
Measure Description	Unified Parkinson's Disease Rating Scale (UPDRS) is a standardized assessment of the symptoms and signs of Parkinson's Disease. Part III assesses motor activity, based on 14 items, such as gait, facial expression, and rigidity. Participants receive a score of 0-4 points per item, with a higher score indicating more severe symptoms. Range of possible total scores, 0 to 56. ON state is when medication is providing benefits with regard to stiffness, slowness, and tremor.
Time Frame	Baseline, Week 0, Week 12, Week 24, Week 36, Week 52, Week 78, Week 104, Week 130, Week 156
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy Population

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-E044-204). Subjects started on perampanel 1mg once daily for 4 weeks, followed by 2mg once daily for 2 weeks; if they did not tolerate the 1 mg dose, subjects were withdrawn from the study. Subjects could be up-titrated to 3 or 4 mg in a sequential manner. There were at least 2 weeks between each titration to assess safety and tolerability, and the subjects attended a clinic visit for safety review and dispensing of more medication. Subjects could be down-titrated at any time to either 3, 2 or 1 mg in a sequential manner.
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Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)**
Participants Analyzed [Units: Participants]	**45**	**125**
Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study [Units: Scores on scale] Mean (Standard Deviation)		
Week 0	**2.30 (6.360)**	**1.46 (7.501)**
Week 12	**2.45 (6.926)**	**0.36 (7.137)**
Week 24	**2.43 (7.247)**	**1.80 (7.912)**
Week 36	**2.69 (8.177)**	**2.78 (9.602)**
Week 52	**2.76 (6.947)**	**3.83 (9.084)**

Week 78	3.64 (7.279)	3.43 (9.344)
Week 104	6.25 (9.345)	4.11 (10.999)
Week 130	6.05 (9.610)	2.77 (9.680)
Week 156	5.72 (8.115)	4.20 (9.034)

No statistical analysis provided for Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Treatment emergent adverse events (TEAE) are those that start on or after the first day of dosing with study medication in the open label extension study, and no later than 30 days after the last day of dosing with study medication.
Additional Description	No text entered.

Reporting Groups

	Description
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Serious Adverse Events

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)
Total, serious adverse events		
# participants affected / at risk	13/48 (27.08%)	39/134 (29.10%)
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	0/48 (0.00%)	2/134 (1.49%)
Cardiac disorders		
Angina unstable † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Atrial fibrillation † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)

Cardiac failure † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Cardiac failure congestive † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Gastrointestinal disorders		
Epigastric discomfort † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Inguinal hernia † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
General disorders		
Gait disturbance † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
General physical health deterioration † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Hernia † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Sudden death † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Hepatobiliary disorders		
Cholelithiasis † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Infections and infestations		
Infection † 1		
# participants affected / at risk	0/48 (0.00%)	2/134 (1.49%)
Pneumonia † 1		
# participants affected / at risk	1/48 (2.08%)	1/134 (0.75%)
Injury, poisoning and procedural complications		
Hip fracture † 1		
# participants affected / at risk	1/48 (2.08%)	1/134 (0.75%)
Device malfunction † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Femur fracture † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Head injury † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Humerous fracture † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Lumbar vertebral fracture † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Radial nerve injury † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
† 1		

Spinal fracture		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Ulna fracture † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Investigations		
Blood alkaline phosphatase † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Blood pressure decrease † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Heamatocrit decreased † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Investigation † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Metabolism and nutrition disorders		
Cachexia † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Musculoskeletal and connective tissue disorders		
Muscle rigidity † 1		
# participants affected / at risk	3/48 (6.25%)	0/134 (0.00%)
Back pain † 1		
# participants affected / at risk	1/48 (2.08%)	1/134 (0.75%)
Posture abnormal † 1		
# participants affected / at risk	2/48 (4.17%)	0/134 (0.00%)
Joint range of motion decreased † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Osteoarthritis † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Pain in extremity † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Sensation of heaviness † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Spinal column stenosis † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Benign ovarian tumor † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Gastrointestinal stromal tumour † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Prostrate cancer † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Rectal cancer † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Uterine cancer † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Nervous system disorders		

Dyskinesia † 1		
# participants affected / at risk	0/48 (0.00%)	3/134 (2.24%)
On and off phenomenon † 1		
# participants affected / at risk	1/48 (2.08%)	2/134 (1.49%)
Dementia † 1		
# participants affected / at risk	0/48 (0.00%)	2/134 (1.49%)
Balance disorder † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Cerebrovascular accident † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Dystonia † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Freezing phenomenon † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Hyperkinesia † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Paraparesis † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Psycomotor hyperactivity † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Sciatica † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Transient ischemic attack † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Tremor † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Psychiatric disorders		
Hallucination † 1		
# participants affected / at risk	1/48 (2.08%)	3/134 (2.24%)
Confusional state † 1		
# participants affected / at risk	0/48 (0.00%)	2/134 (1.49%)
Hallucination, visual † 1		
# participants affected / at risk	1/48 (2.08%)	1/134 (0.75%)
Psychotic disorder † 1		
# participants affected / at risk	0/48 (0.00%)	2/134 (1.49%)
Delirium † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Delusion † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Dissociation † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Insomnia † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Renal and urinary disorders		
Obstructive uropathy † 1		

# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Urinary retention † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary embolism † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Pulmonary oedema † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Social circumstances		
Social stay hospitalisation † 1		
# participants affected / at risk	1/48 (2.08%)	1/134 (0.75%)
Surgical and medical procedures		
Deep brain stimulation † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Knee arthroplasty † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	0/48 (0.00%)	2/134 (1.49%)
Arterial stenosis limb † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)
Hypotension † 1		
# participants affected / at risk	1/48 (2.08%)	0/134 (0.00%)
Orthostatic hypotension † 1		
# participants affected / at risk	0/48 (0.00%)	1/134 (0.75%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA version 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Treatment emergent adverse events (TEAE) are those that start on or after the first day of dosing with study medication in the open label extension study, and no later than 30 days after the last day of dosing with study medication.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description

Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-E044-204). Subjects started on perampanel 1mg once daily for 4 weeks, followed by 2mg once daily for 2 weeks; if they did not tolerate the 1 mg dose, subjects were withdrawn from the study. Subjects could be up-titrated to 3 or 4 mg in a sequential manner. There were at least 2 weeks between each titration to assess safety and tolerability, and the subjects attended a clinic visit for safety review and dispensing of more medication. Subjects could be down-titrated at any time to either 3, 2 or 1 mg in a sequential manner.
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Other Adverse Events

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 0.5, 1, or 2 mg During Core Study)
Total, other (not including serious) adverse events		
# participants affected / at risk	**3/48 (6.25%)**	**0/134 (0.00%)**
Musculoskeletal and connective tissue disorders		
Muscle Rigidity † 1		
# participants affected / at risk	**3/48 (6.25%)**	**0/134 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA version 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
Due to early termination, no subjects completed this open-label extension study.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Eisai Inc.
Organization: Eisai Call Center
phone: 888-422-4743

Responsible Party:	Eisai Inc.
ClinicalTrials.gov Identifier:	NCT01634360 History of Changes
Other Study ID Numbers:	E2007-E044-205 2004-000361-35 (EudraCT Number)
Study First Received:	July 3, 2012
Results First Received:	October 23, 2012
Last Updated:	June 25, 2014
Health Authority:	European Union: European Medicines Agency

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