A 14-month open-label extension phase of the double-blind, placebo-controlled, dose-escalation, parallel-group studies to evaluate the efficacy and safety of E2007 (perampanel) given as adjunctive therapy in subjects with refractory partial seizures

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON32105

Source
ToetsingOnline

Brief title
E2007-G000-307

Condition

- Seizures (incl subtypes)

Synonym
epilepsy, falling disease

Research involving
Human

Sponsors and support

Primary sponsor: Eisai
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Adjunctive therapy, Epilepsy, Perampanel, Refractory Partial Seizures

Outcome measures

Primary outcome

For subjects who were assigned to the perampanel treatment arms during the preceding double-blind studies, the following variables will be analyzed over the Double-blind Phase plus the Open-label Treatment Phase (Conversion Period + Maintenance Period) relative to Pre-randomization Phase of the double-blind study. For subjects who were assigned to the placebo arms during the double-blind studies, the following variables will only be analyzed over the Open-label Treatment Phase (Conversion Period + Maintenance Period) relative to Pre-randomization Phase of the double-blind study:

1. Percent change in seizure frequency per 28 days

2. Proportion of patient who experience a 50% or greater reduction in seizure frequency per 28 days (responder rate analysis)

3. Percent change in seizure frequency per 28 days per seizure type

Secondary outcome

The safety will be examined based on nature, frequency, and severity of adverse events, chemistry and hematology laboratory test results, vital signs, and

12-lead ECG abnormalities over the perampanel treatment period

Study description

Background summary

Epilepsy is a common, serious neurological disorder. Epilepsy is characterized by the spontaneous recurrence of seizures and requires long-term, often life-long, pharmacological treatment. In general there are 2 types of seizures and the most frequent type is partial seizures. Patients suffering from partial seizures often have poor seizure control. This leads to a wide variety of medical consequences (e.g., severe trauma due to the seizure, sudden death, depression, psychotic disorders). In addition, uncontrolled seizures have a large impact on the lifestyle and lead to social handicaps (e.g., loss of driving privileges and difficulties getting and/or maintaining a job).

Over the past 15 years, several new anti-epileptic drugs have appeared on the market with the objective of improving efficacy, tolerability and ease use when compared with the classical anti-epileptic drugs. Although the medications are efficacious and relatively safe, they do not meet the treatment needs of patients with epilepsy among other things apparently due the following:
- In over 30% of the patients the seizures are poorly controlled with current treatment
- 25% of the patients starting with a certain anti-epileptic drug have to abandon treatment as a result of serious side effects and a much higher number suffer from chronic side effects that will limit their quality of life
- various epilepsy syndromes appear completely resistant to standard therapies.

From the above, the need for the development of new anti-epileptic drugs with improved efficacy and tolerability is needed.

Study objective

The primary objective is to evaluate the safety and tolerability of perampanel (up to12mg/day) given as adjunctive treatment in subjects with refractory partial seizures
The secondary objective is to evaluate the maintenance of effect of perampanel for the control of refractory partial seizures.

Study design

open-label extension study

Intervention

The study can be divided in 2 parts:
A conversion period:
All patients will take during this period once a day 6 tablets. These tablets consists of 2 mg perampanel tablets and/or placebo tablets. The patients will start with the dose that they received in the preceding study (except those that received placebo, they will start with 2 mg) and this dose will be up-titrated every 2 weeks with 2 mg until the optimal dose is reached.

B Maintenance period:
The patient will take 2 mg and/or 4mg tablets

Study burden and risks

Extent of burden:
Patients are asked to visit the research location 10 times in a period of 14 months.
Patients are asked to keep a diary about the frequency of seizures and the number of side effects.
Between every visit there will be a telephone contact, to remind the patient to keep the diary etc.
Women of childbearing potential must agree to be abstinent or continue using at least 1 medically acceptable method of contraception throughout the entire study periode and for 2 months after the last dose of study drug.
In addition the following assessments will take place:
3 x complete physical exam
3 x complete neurological exam
10 x vital signs (pulse and blood pressure)
10 x determine body weight (at screening also length)
5 x ECG
5 x blood draw

Risks:
Risks on side effects:
Neurological side effects: sleepiness; dizziness; sedation; vertigo; tingling in nerves; and difficulty moving; difficulty walking; abnormal movements; and other worsening of the symptoms of known Parkinson's disease.
Gastro-intestinal side effects: abdominal pain; vomiting; constipation; diarrhoea.
Other side effects: falls; insomnia; an increase in blood pressure; fatigue; increased rigidity in joints; muscle cramps; depression; and itching of the skin.

Risks of drawing blood:
May cause local pain, bruising, bleeding, blood clot formation, and, in rare

instances, an infection might occur at the site where blood is drawn. There is also the possibility of dizziness or fainting while your blood is being drawn.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Have completed visit 8 of study E2007-G000-304, E2007-G000-305 or E2007-G000-306 and shown compliance with the inclusion and exclusion criteria for that study (exluding criteria that are related to seizure occurences)
- Continue to be treated with a stable dose of 1 or maximum of 3 approved AEDs

Exclusion criteria

- Those who, for any reason, discontinued early from the preceding double-blind study

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2009
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	perampanel

Ethics review

Approved WMO

Date:	19-09-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	09-01-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	25-03-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	11-06-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	01-07-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	25-08-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	15-09-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	30-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	18-02-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-06-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-01-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-03-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-03-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	12-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-006170-28-NL
CCMO	NL23258.040.08