An Open-Label, Multicenter, Extension Study To Evaluate The Long-Term Safety, Tolerability, And Efficacy Of UCB0942 When Used As Adjunctive Therapy For Partial Onset Seizures In Adult Subjects With Highly Drug-Resistant Focal Epilepsy

Published: 23-07-2015
Last updated: 20-04-2024

In this extension study, the long-term safety, tolerability and efficacy of UCB0942 will be studied when used as an adjunctive therapy for partial seizures in adult volunteers with high drug resistant partial epilepsy.

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

Summary

ID

NL-OMON50315

Source
ToetsingOnline

Brief title
UCB0942 Open-Label Extension Study (EP0073)

Condition

- Seizures (incl subtypes)

Synonym
epileptic seizures, focal epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: UCB Biopharma SRL
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Focal Epilepsy

Outcome measures

Primary outcome

- To evaluate the long-term safety and tolerability of UCB0942 at

individualized doses between 100mg/day to a maximum of 800mg/day in subjects

with highly drug-resistant focal epilepsy.

Secondary outcome

- To evaluate the long-term efficacy of UCB0942

- To evaluate the effects of UCB0942 on the subject*s quality of life.

Study description

Background summary

UCB0942 is a medicinal product which is currently being evaluated as an antiepileptic drug in clinical studies. It has not yet been approved by the authorities for the treatment of any disease, including focal epilepsy. Studies in animals suggest that UCB0942 may have anti-seizure effects in humans. Patients participating in the blinded study (NL53484.056.15) will have the oppurtunity to, when criteria are met, to continue the treatment in this study.

Study objective

In this extension study, the long-term safety, tolerability and efficacy of UCB0942 will be studied when used as an adjunctive therapy for partial seizures

in adult volunteers with high drug resistant partial epilepsy.

Study design

This study consists of an examination period (2 weeks), an investigation period up to approximately 5 years, a phasing-out period (about 3 weeks) and a follow-up period (4 weeks). The maximum duration is approximately 5 years or until the compound has been approved for the treatment of epilepsy or until the sponsor decides to stop the study (when there is a risk to your safety or lack of efficacy). The volunteer will continue with the treatment that has been initiated in the EP0069 study; twice daily dosing UCB0942. During the study, the study physician can raise or lower the dose of UCB0942 to increase the tolerability and effectiveness.

Intervention

Please refer to the section 'study design'

Study burden and risks

N/A

Contacts

Public
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Brussels 1070
BE
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Subject must have completed V13 of the Outpatient Maintenance Period of EP0069 to be eligible for enrollment into EP0073.
- In EP0069, the subject demonstrated a reduction in frequency and/or severity of seizures as compared to baseline that is considered clinically significant by the Investigator and significant by the subject.
- In EP0069, the subject experiences substantial benefit from UCB0942 with acceptabletolerability according to the subject and Investigator.
- Male subject confirms that, during the study period and for a period of 3 months after the final dose, when having sexual intercourse with a woman of childbearing potential, he will use a barrier contraceptive (eg, condom).

Exclusion criteria

- Subject has developed a known hypersensitivity to any components of the investigational medicinal product (IMP) as stated in this protocol during participation in EP0069.
- Subject has any severe medical, neurological, or psychiatric condition, or laboratory value which may have an impact on the safety of the subject.
- Subject is a woman who is pregnant or lactating.
- Subject has active suicidal ideation as indicated by a positive response (*Yes*) to either Question 4 or Question 5 of the *Since Last Visit* version of the C-SSRS. The subject should be referred immediately to a Mental Healthcare Professional and must be withdrawn from the study.
- Subject has taken other (non-AED) prescription, non-prescription, dietary (eg, grapefruit or passion fruit), or herbal products that are potent inducers or inhibitors of the CYP3A4 pathway for 2 weeks (or 5 half-lives whichever is longer) prior to study entry.
- Subject has an abnormality in the 12-lead ECG that, in the opinion of the Investigator, increases the risks associated with participating in the study.
In addition, any subject with any of the following findings will be excluded:
* Prolonged QTc (Bazett*s, machine-read) interval defined as >450ms for males

and >470ms for females
* Bundle branch blocks and other conduction abnormalities other than mild first degree atrioventricular block (defined as PR interval *220ms)
* Irregular rhythms other than sinus arrhythmia or occasional, rare supraventricular or rare ventricular ectopic beats
* In the judgment of the Investigator, T-wave configurations are not of sufficient quality for assessing QT interval duration
- Subject has a clinically significant abnormality on echocardiography at the EV (V2) of EP0073.
- Subject has >2x upper limit of normal (ULN) of any of the following: alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), or >ULN total bilirubin (*1.5xULN total bilirubin if known Gilbert*s syndrome) at the EV (V2) of EP0073 (V15 of EP0069). If subject has elevations only in total bilirubin that are >ULN and <1.5xULN, fractionate bilirubin to identify possible undiagnosed Gilbert*s syndrome (ie, direct bilirubin <35%).
- For enrolled subjects with a baseline result >ULN for ALT, AST, ALP, or total bilirubin, a baseline diagnosis and/or the cause of any clinically meaningful elevation must be understood and recorded in the electronic Case Report form (eCRF).
If subject has >ULN ALT, AST, or ALP that does not meet the exclusion limit at screening (ie, the value is >ULN but *2xULN at the EV [V2] of EP0073), repeat the tests, if possible, prior to dosing to ensure there is no further ongoing clinically relevant increase. In case of a clinically relevant increase, inclusion of the subject must be discussed with the Medical Monitor.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2015
Enrollment:	9

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Padsevonil
Generic name:	nvt

Ethics review

Approved WMO Date:	23-07-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-08-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-01-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-02-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-02-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-05-2016
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-02-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-01-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-03-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-07-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	21-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-03-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-03-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2015□001268□20-NL
CCMO	NL54291.056.15