A Long-Term Extension Study of the Safety and Tolerability of RVT-101 in Subjects with Dementia with Lewy Bodies (DLB)

Published: 24-11-2016
Last updated: 31-12-2024

To assess the long-term safety and tolerability of 35 mg and 70 mg RVT-101 in subjects with DLB

Ethical review	Approved WMO
Status	Completed
Health condition type	Mental impairment disorders
Study type	Observational invasive

Summary

ID

NL-OMON45315

Source
ToetsingOnline

Brief title
RVT-101-2002

Condition

- Mental impairment disorders

Synonym
Dement¡a with Lôwy Bodies. Dementia with Lewy bodies (DLB) is a type of demenlia that shares symptoms with both Alzheimer's disease and Park¡nson's disease.

Research involving
Human

Sponsors and support

Primary sponsor: PPD

Source(s) of monetary or material Support: Axovant

Intervention

Keyword: Central nervous system, Dementia with Lewy bodies

Outcome measures

Primary outcome

Safety evaluation: Safety will be evaluated based on adverse events (AEs), physical and neurological examinations, vital signs (including measurements of orthostatic changes in blood pressure [BP] and heart rate [HR]), electrocardiograms (ECGs), questionnaire for signs of potential orthostasis (QSO), Columbia-Suicide Severity Rating Scale (C-SSRS) and clinical laboratory assessments.

Secondary outcome

None

Study description

Background summary

This RVT-101-2002 study is an extension study to the RVT-101-2001 to investigate how well RVT-101 works to improve cognitive and overall function as well as to investigate the safety of RVT-101. The present study is to the Safety and Tolerability of RVT-101 in the same subjects who participated in the RVT-101-2001 study.
It is believed that patients with dementia with Lewy bodies have an imbalance of acetylcholine, which is a chemical in the brain thought to be responsible for cognition. RVT-101 promotes the release of acetylcholine in the brain, RVT-101 is in the RVT-101-2001 phase 2b study tested to assess whether the drug can promote cognitive and overall functioning in patients with Lewy Body Dementia.

Study objective

To assess the long-term safety and tolerability of 35 mg and 70 mg RVT-101 in subjects with DLB

Study design

This is a multi-center extension study. The safety and tolerability of RVT-101 at doses of 35 mg and 70 mg daily will be evaluated over a 24-week treatment period in subjects with probable DLB who have participated in Study RVT-101-2001, *A Phase 2b, double-blind, randomized, placebo-controlled study of RVT-101 in subjects with dementia with Lewy bodies (DLB).* Subjects who were randomized to treatment arms RVT-101 35 mg and RVT-101 70 mg in Study RVT-101-2001 will remain in those same treatment groups for this study, while subjects who were randomized to placebo in Study RVT-101-2001 will be assigned to the RVT-101 70 mg treatment group. Treatment assignments for this study will be double-blind until Study RVT-101-2001 database is locked and unblinded; after that the treatment assignments will be double-blind, but Sponsor-open, meaning the subject and investigator will not know what treatment assignment he/she has been given but the Sponsor and its representatives will.

Study burden and risks

Burden, - questionnaires blood drawn at 7 visits, physical exam. See section 8.1 Study assessments and procedures van protocol v1.0 dd 23May2016.
As with taking any drug, there is a risk of allergic reaction. Some things that may happen during an allergic reaction are:
. Rash or hives
. Having a hard time breathing
. Wheezing when you breathe
. Sudden change in blood pressure, which may make you feel dizzy or lightheaded
. Swelling around the mouth, throat or eyes
. Fast pulse
. Sweating
The study may provide scientific data useful in the future.

Contacts

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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

1. Male or female subjects who have completed the last on-treatment visit (Visit 12) of the lead-in study (RVT-101-2001). Subjects who were prematurely discontinued from the lead-in study may be enrolled in this study only after discussion with the Medical Monitor. The number of subjects enrolled in this study who did not complete the lead-in study (RVT-101-2001) will be capped at 12.
2. If the subject is currently receiving any of the following medications or non-medication therapies, the treatment regimen has been stable (i.e., no changes in the type of drug, dose or frequency of dosing) for at least 30 days prior to the Screening/Baseline Visit and there is no intent to change this treatment regimen up to Visit 4 of this study.
• Acetylcholinesterase inhibitors
• Memantine
• Axona® (caprylidene)
• Antidepressants (other than MAO inhibitors)
• Thyroid hormones
• Atypical antipsychotics
• Benzodiazepines and other sedatives/hypnotics
Note: Benzodiazepines or other sedatives/hypnotics (including antihistamines) with half-life less than 6 hours can be taken on an as needed basis.
• Cognitive tasks for cognitive rehabilitation under medical supervision
• Neurostimulation;5. Subject continues to be able to ingest pills (in tablet form) whole.
6. Subject has a caregiver who has signed an agreement to oversee the subject*s compliance with IP and protocol-specified procedures and report on subject*s health status.

Exclusion criteria

1. Subject who, at Visit 1, is experiencing an ongoing, uncontrolled AE(s) from the lead-in study (RVT-101-2001) or did experience an uncontrolled AE in the lead-in study (RVT-101-2001) that might prevent the subject from safely participating in the study in the opinion of the investigator. Subjects who experienced an SAE that was deemed related, possibly related or probably related to IP during the lead-in study may be considered for participation in this study only after discussion with the Medical Monitor.
2. Subject who, in the opinion of the investigator, had a clinically significant vital sign or ECG abnormality at Visit 12 of the lead-in study, or at the Screening/Baseline visit for this study, that would prevent the subject from safely participating in this study.
3. Subject who, in the opinion of the investigator, had a clinically significant laboratory abnormality at Visit 11 or Visit 12 of the lead-in study, or at the Screening/Baseline visit for this study, that would prevent the subject from safely participating in this study. Investigators need not wait for laboratory results at Visit 12 of the lead-in study or the Screening/Baseline Visit of this study before enrolling the subject in this study. However, any clinically significant abnormality subsequently identified from Visit 12 of the lead-in study and/or at the Screening/Baseline visit for this study will be evaluated by the investigator and the subject assessed for continued participation.
4. Subject who, in the opinion of the investigator, has any confounding medical or psychiatric condition that would prevent the subject from safely participating in this study.
5. Significant suicide risk as defined by (a) suicidal ideation as endorsed on items 4 or 5 of the suicidal ideation section of the Since Last Visit version C-SSRS at the Screening/Baseline visit of this study or (b) any suicidal behaviour endorsed on the Since Last Visit version of the C-SSRS at the Screening/Baseline visit of this study, or (c) clinical assessment of significant suicidal risk.
6. Treatment with any concomitant medication detailed in Table 1. Prohibited medications as outlined in Table 1 unless otherwise specified, need to have been discontinued for 5 half-lives prior to the Screening/Baseline Visit and assessed as no longer clinically necessary for the subject.
7. Confirmed corrected QT interval (QTc) value >= 450 msec for males or >= 470 msec for females at the Screening/Baseline visit for this study. Subjects with a QRS value greater than 120 msec and subjects with a QTc value less than 500 msec may be eligible following discussion with the Medical Monitor.
8. Subject who, in the investigator*s opinion, is unable to take the IP product as directed throughout the study (with assistance is acceptable) or who has demonstrated significant non-compliance with IP in the lead-in study (RVT-101-2001).
9. Subject or caregiver is an immediate family member or employee of the participating investigator, any of the participating site staff, or of the sponsor study staff.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-05-2017
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	RVT-101
Generic name:	RVT-101
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-11-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-05-2017
Application type:	First submission
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	EUCTR2016-002412-40-NL
CCMO	NL59450.056.16

Study results

Date completed: 09-02-2018

Results posted: 20-08-2019

First publication
15-02-2019