A 52-Week, open-label, single-arm study to evaluate the safety and tolerability of 24-hour daily exposure of continuous subcutaneous infusion of ABBV-951 in subjects with Parkinson*s disease

Published: 27-03-2019
Last updated: 25-03-2025

To assess the local and systemic safety and tolerability of ABBV-951 delivered as a CSCI for 24 hours daily for up to 52 weeks.

Ethical review	Approved WMO
Status	Completed
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON55829

Source
ToetsingOnline

Brief title
M15-741

Condition

- Movement disorders (incl parkinsonism)

Synonym
paralysis agitans, shaking palsy

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Drug Tolerance, Injections, Parkinson disease, Safety, Subcutaneous

Outcome measures

Primary outcome

1. Percentage of subjects with adverse events (AEs) and serious adverse events (SAEs) during the study

2. Percentage of subjects with AEs of special interest (AESIs) during the study

3. Percentage of subjects with numeric grade equal to or higher than 5 and percentage of subjects with letter grade equal to or higher than D on the Infusion Site Evaluation Scale at any time during the study

4. Change in clinical laboratory test data from Baseline to end of study

5. Change in vital sign measurements from Baseline to end of study

6. Change in electrocardiograms (ECGs) from Baseline to end of study

Secondary outcome

Change from Baseline to end of study for the following:

1. Average normalized daily "Off" time and "On" times as assessed by the PD Diary

2. PD symptoms as assessed by the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Parts I-IV (or the UPDRS Parts I-V in countries where a validated translation of the MDS-UPDRS is not available)

3. Sleep symptoms as assessed by the PD Sleep Scale-2 (PDSS-2)

4. Quality of life as assessed by the PD Questionnaire-39 items (PDQ-39)

5. Health-related quality of life as assessed by the EuroQol 5-dimensions

questionnaire (EQ-5D-5L)

Study description

Background summary

ABBV-951 is a soluble formulation of carbidopa/levodopa that is deliverable by continuous subcutaneous infusion. ABBV-951 has the potential to achieve efficacy similar to levodopa-carbidopa intestinal gel (LCIG) in patients with Parkinson's disease (PD) by delivering a much smaller volume in a less invasive approach than LCIG. This study is conducted to assess the safety and tolerability of the long-term use of ABBV-951 in PD patients, whose motor symptoms are inadequately controlled by their current treatment.

Study objective

To assess the local and systemic safety and tolerability of ABBV-951 delivered as a CSCI for 24 hours daily for up to 52 weeks.

Study design

Open-label, single arm study

Intervention

ABBV-951 solution for infusion

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
ABBV-951 is an investigational drug containing levodopa and carbidopa. This is usually dosed in tablets or via intestinal gel (LCIG). ABBV-951 is a soluble form of levodopa/carbidopa that can be distributed via subcutaneous infusion. Risks associated with participation are risks involving study procedures and risks associated with the study drug dispensation via subcutaneous infusion. Side effects of ABBV-951 are comparable to side effects of levodopa/carbidopa oral tablets or intestinal gel.
The burden for study participants exists of attending study visits, completing

disease and dosing diaries between the visits and the training for the ABBV-951 dosing system.

Contacts

Public
AbbVie Deutschland GmbH & Co. KG

Knollstrasse 70
Ludwigshafen 67061
DE
Scientific
AbbVie Deutschland GmbH & Co. KG

Knollstrasse 70
Ludwigshafen 67061
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult male or female subjects, 30 years of age or older at the time of screening, with a diagnosis of idiopathic PD that is levodopa-responsive

Exclusion criteria

Subjects judged by the investigator to be adequately controlled by current

therapy, that don't have recognizable/identifiable "Off" and "On" states (motor fluctuations), and have less than 2.5 hours of "Off" time per day.

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-12-2019
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-951
Generic name:	ABBV-951

Ethics review

Approved WMO Date:	27-03-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-08-2019

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-09-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-10-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-06-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2018-002144-85-NL
ClinicalTrials.gov	NCT03781167
CCMO	NL68350.078.19

Study results

Date completed: 16-12-2020

Results posted: 22-09-2023

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File