An open-label extension of Study M15-741 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: 06-10-2020
Last updated: 09-04-2024

To assess the local and systemic safety and tolerability of continued ABBV-951 treatment delivered as a CSCI for 24 hours daily.

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

Summary

ID

NL-OMON52546

Source
ToetsingOnline

Brief title
M15-737

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 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 the end of study

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

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

Secondary outcome

Change from Baseline to the 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

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

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

questionnaire (EQ-5D-5L)

5. Cognitive impairment as assessed by the Mini-Mental State Examination (MMSE)

Study description

Background summary

Parkinson's disease (PD) is a neurological condition, which affects the brain. PD gets worse over time, but how quickly it progresses varies a lot from person to person. Some symptoms of PD are tremors, stiffness, and slowness of movement.

Study objective

To assess the local and systemic safety and tolerability of continued ABBV-951 treatment delivered as a CSCI for 24 hours daily.

Study design

Open-label, single arm, extension study

Intervention

Participants will receive continuous subcutaneous infusion (CSCI) of ABBV-951 for 24 hours daily for 96 weeks or until premature discontinuation.

Study burden and risks

There may be higher treatment burden for participants in this trial compared to their standard of care. Participants will attend regular clinic visits and remote assessments during the course of the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, checking for side effects, and completing questionnaires.

Contacts

Public
AbbVie Deutschland GmbH & Co. KG

Knolsstrasse 70
Ludwigshafen 67061

DE
Scientific
AbbVie Deutschland GmbH & Co. KG

Knolsstrasse 70
Ludwigshafen 67061
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject must be able to understand the nature of the study and have had the opportunity to have any questions answered by the investigator.
2. Subject, if judged by the investigator to have decision making capacity, must voluntarily sign and date an informed consent form approved by an independent ethics committee (IEC)/institutional review board (IRB), prior to initiation of any study-specific procedures.
3. Subject completed ABBV-951 Study M15-741 (parent study) and remained on study drug.
4. Subject is willing and able to comply with procedures required in this protocol.
5. Subject is not considered by the investigator to be an unsuitable candidate to continue to receive ABBV-951 for any reason.
6. Subject does not
currently exhibit significant suicidal behavior (suicidal behavior is evidenced by answering "yes"
to any question on the suicidal behavior portion of the C-SSRS) or suicidal ideation (suicidal
ideation is evidenced by answering "yes" to Questions 4 or 5 on the suicidal ideation portion of
the C-SSRS) at the Final Visit of the parent study. Subjects who exhibit

suicidality during the
course of the parent study prior to the Final Visit are eligible based on the Investigator's
judgment.
7. If female, subject must be either postmenopausal, OR permanently surgically sterile OR for women of childbearing potential practicing at least 1 protocol-specified method of birth control that is effective from D1 through at least 30 days after the end of the infusion of study drug. Subject is not pregnant, breastfeeding, or considering becoming pregnant or donating eggs during the study or within 30 days after the end of the infusion of study drug. If female of childbearing potential, subject must have a negative urine pregnancy test on D1.
8. If male and sexually active with a female partner(s) of childbearing potential, subject must agree to practice protocol-specified contraception. Subject is not considering fathering a child or donating sperm during the study or within 30 days after the end of the infusion of study drug.

Exclusion criteria

1. Subject has received an investigational product other than ABBV-951 within a time period equal to 5 half-lives, if known, or within 6 weeks, whichever is longer, prior to study drug administration.

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):	16-12-2020
Enrollment:	2

Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	06-10-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-10-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-11-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-06-2021

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-06-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-07-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-01-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-02-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-02-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-04-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	05-11-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-12-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-03-2023

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-05-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-08-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-09-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	EUCTR2019-004235-23-NL
ClinicalTrials.gov	NCT04379050
CCMO	NL73757.028.20