A Phase 2b, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of BIIB122 in Participants with Parkinson*s Disease

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This study has been transitioned to CTIS with ID 2023-505645-12-00 check the CTIS register for the current data. Main objective: To evaluate the efficacy of BIIB122 225 mg compared with placebo.Secondary objective: To evaluate the efficacy, safety...

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

Summary

ID

NL-OMON51537

Source
ToetsingOnline

Brief title
283PD201

Condition

- Movement disorders (incl parkinsonism)

Synonym
paralysis agitans, primary parkinsonism

Research involving
Human

Sponsors and support

Primary sponsor: Biogen
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: LRRK2, Parkinson

Outcome measures

Primary outcome

Time to confirmed worsening in Movement Disorder Society Unified Parkinson*s Disease Rating Scale (MDS-UPDRS) Parts II and III combined score over the treatment period.

Secondary outcome

• Incidence of AEs and SAEs during the treatment period

• Time to confirmed worsening in MDS-UPDRS Part II score over the treatment period

• Change in MDS-UPDRS Parts II and III combined score

• Time to confirmed worsening in Schwab and England Activities of Daily Living Scale (SEADL) over the treatment period

• Change in MDS-UPDRS Parts I, II, and III combined score

Study description

Background summary

This Phase 2b, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study is designed to determine the efficacy and safety of BIIB122 in Participants with Parkinson*s Disease

Study objective

This study has been transitioned to CTIS with ID 2023-505645-12-00 check the CTIS register for the current data.

Main objective:
To evaluate the efficacy of BIIB122 225 mg compared with placebo.

Secondary objective:
To evaluate the efficacy, safety and tolerability of BIIB122 225 mg compared with placebo in participants with early-stage PD

Objective optional (non-mandatory) biofluid sub-study
The objective of the biofluid substudy is to evaluate the change in central and peripheral biomarkers over time. Collection will include repeat LPs for CSF only or CSF and blood sampling for PBMC.

Study design

This Phase 2b, multicenter, randomized, double-blind, placebo-controlled, parallel-group study is designed to evaluate the efficacy and safety of BIIB122 in participants with early-stage PD. The study population is defined as participants with a clinical diagnosis of PD within the past 2 years who do not carry a pathogenic variant in the LRRK2 gene.

Optional (non-mandatory) biofluid sub-study
A biofluid substudy may be conducted to evaluate exploratory biofluid biomarkers in a subset of participants.All biofluid substudy participants are planned to participate in the CSF portion of the substudy. A subset of those participants that particpate in the CSF portion of the substudy will also participate in the PBMC portion of the substudy. Samples will be evaluated for measures of LRRK2 pathway, lysosomal function, and exploratory measures relevant to PD.

Optional (non-mandatory) genetic research
Participants will be offered the option for residual DNA samples to be retained for future exploratory genetic research that may be used to understand the biology of diseases and traits of interest to the Sponsor and/or to develop diagnostic and analytical tests.Participation in genetic research does not involve additional visits for the participant.

Intervention

Eligible participants will be randomly assigned in a 1:1 ratio to receive BIIB122 225 mg or matching placebo tablets orally QD during the double-blind, placebo-controlled treatment period.

Study burden and risks

Participants will participate in the study for the duration up to 152 weeks. Subjects will need to come to the hospital more often than they normally would and they undergo additional tests. These include physical and neurological examination, Dat/SPECT scan, respiratory assessments, ECG*s, pregnancy tests, urine/blood tests and questionnaires. Subjects will receive medication orally and subjects cannot be pregnant at the start or during the study. Aside from these interventions, participation in this study involves blood draws (venapunction) and in the course of the study 390 ml up to 535 ml blood will be taken.

Risks associated with the study drugs include allergy-related reactions. Common side effects of BIIB122 include headache, fatigue (feeling tired), nausea (feeling of having to vomit), vomiting, muscle pain, dizziness, back pain, diarrhea, nasopharyngitis (common cold), flu-like symptoms and difficulty in sleeping. Subject may also feel discomfort during some of the tests.

Furthermore the subjects more receptive to risks such as;
• Blood collection: Pain and/or bruising at the needle site of puncture. Although very rare, localized clot formation and infections may occur.
• ECG: skin irritation is rare but could occur from the electrodes or gel that is used.
• Mental health assessments: As some of the questionnaires/scales used in this study will ask questions about subjects feelings, mental health and well-being, subject experience these as distressing.

In conclusion, the risks identified from nonclinical and clinical safety studies are manageable. Given the unmet need for a therapeutic treatment that may slow the progression of PD, BIIB122 has an overall favorable benefit-risk profile supporting further continued development of BIIB122 in PD patients.

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

Key Inclusion Criteria:
• Clinical diagnosis of PD meeting the Movement Disorder Society Clinical Diagnostic Criteria within 2 years of the screening visit, inclusive, and at least 30 years of age at the time of diagnosis
• Modified Hoehn and Yahr scale, stages 1 to 2 (in OFF state), inclusive
• MDS-UPDRS Parts II and III (in OFF state) combined score less than or equal to (<=)40 at screening
• Screening genetic test results verifying the absence of a pathogenic leucine-rich repeat kinase 2 (LRRK2) variant (i.e., G2019S, N1437H, R1441G, R1441C, R1441H, Y1699C, or I2020T). Participants with additional LRRK2 variants may be excluded if data emerge to convincingly support an association of the variants with LRRK2-PD pathogenicity.

NOTE: Other protocol defined Inclusion criteria may apply. See Protocol section 6.1.

Exclusion criteria

Key Exclusion Criteria:
• Clinically significant neurological disorder other than PD, including but not limited to stroke, dementia, or seizure, within 5 years of screening visit, in the opinion of the Investigator
• Clinical evidence of atypical parkinsonism (e.g., multiple-system atrophy or progressive supranuclear palsy) or evidence of drug-induced parkinsonism.
• Montreal Cognitive Assessment (MoCA) score <24 at the screening visit

NOTE: Other protocol defined Exclusion criteria may apply. See Protocol section

6.2

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	23-11-2022
Enrollment:	13
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	N/A
Generic name:	BIIB122

Ethics review

Approved WMO

Date:	27-06-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	10-11-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-05-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-09-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-02-2024
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
EU-CTR	CTIS2023-505645-12-00
EudraCT	EUCTR2021-004849-20-NL
ClinicalTrials.gov	NCT05348785

Register	ID
CCMO	NL80677.056.22