ISRCTN12870393 https://doi.org/10.1186/ISRCTN12870393

A randomised, double-blind, placebo-controlled, dose escalation study of single and multiple oral dose administration of BIIB014 in subjects with moderate to late stage parkinson's disease who are also receiving treatment with levodopa

Submission date	Recruitment status	[X] Prospectively registered
08/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/04/2014	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
204PD202

Study information

Scientific Title

Study objectives
To establish a safe and tolerable BIIB014 dose range for future studies in subjects with moderate to late stage Parkinson's Disease (PD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Thames Valley Multi-Centre Research Ethics Committee (ref: 06/MRE12/67)

Ethics approval added as of 04/07/2007:
Nizam's Institute of Medical Sciences (India) (ref: EC/NIMS/702©/2007)

Study design
Double-blind, placebo-controlled, multicentre, dose-escalation, single dose/washout/multiple dose study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Moderate to late stage Parkinson's Disease (PD)

Interventions
Please note that this trial started in May 2007 and the anticipated trial end date has been extended to March 2008.

Group one: Intervention treatment - BIIB014 at either 5 mg, 5 mg/10 mg, 10 mg, 10 mg/30 mg, 30 mg, 30 mg/100 mg, 50 mg, 100 mg. If patients are randomised to a single dose group they will receive 26 days of treatment (72 hour washout after first dose). If patients are randomised to a two dose group they will receive 28 days of treatment (seven days at the lower dose and 21 days at the higher dose).
Group two: Control treatment - placebo and levodopa treatment. The control group is the standard of care. All doses are in capsule form to be taken once daily in the morning with food.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
BIIB014, levodopa

Primary outcome measure
1. The number and proportion of subjects with adverse events
2. Assessment of clinical laboratory parameters
3. Assessment of vital signs
4. Assessment of ECG parameters

Secondary outcome measures
1. To explore the PharmacoKinetic (PK) drug interactions between BIIB014 and L-DOPA in subjects with moderate to late stage PD
2. To explore the PK of BIIB014 when administered as adjunct therapy to subjects with moderate to late stage PD
3. To explore the activity of BIIB014 when administered as adjunct therapy to subjects with moderate to late stage PD

Overall study start date
31/12/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Inclusion criteria amended as of 18/06/2007:
1. Male or female subjects, aged 30 to 78 years old, inclusive
2. Must carry a diagnosis of idiopathic PD according to UK Parkinson's Disease Society Brain Bank Clinical Diagnostic Criteria made by a Movement Disorder Specialist, and be Hoehn & Yahr Stage II to IV (inclusive) when 'off'
4. Subjects must be on a stable dose of L-3,4-Dihydroxyphenylalanine (L-DOPA) / carbidopaor L-DOPA / benserazide for at least 4 weeks prior to enrollment
5. Some subjects must demonstrate a definite end of L-DOPA dose wearing off (at least two hours 'off' time per waking day) and must be able to keep accurate patient diaries of PD activity
6. Except for L-DOPA and certain allowed dopamine agonists, must not be receiving any other

PD medication (Current treatment with certain dopamine agonists is allowed but must have been on a stable dose for at least 4 weeks prior to enrollment)

Inclusion criteria provided at time of registration:
1. Male or female subjects, aged 30 to 78 years old, inclusive
2. Must carry a diagnosis of idiopathic PD according to UK Parkinson's Disease Society Brain Bank Clinical Diagnostic Criteria made by a Movement Disorder Specialist, and be Hoehn & Yahr Stage II to IV (inclusive) when 'off'
4. Subjects must be on a stable dose of L-3,4-Dihydroxyphenylalanine (L-DOPA)/carbidopa or L-DOPA/benserazide for at least three weeks prior to enrollment
5. Must demonstrate an excellent motor response to L-DOPA, and have a definite end of L-DOPA dose wearing off (at least two hours 'off' time per waking day)
6. Subjects must not be receiving any other PD medications

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
As of 18/06/2007: 90; At time of registration: 110

Key exclusion criteria
Exclusion criteria amended as of 18/06/2007:
1. Mini Mental State Examination (MMSE) score of <26
2. History or clinical features consistent with an atypical parkinsonian syndrome
3. Any significant non-PD central nervous system disorder
4. Any significant AXIS I psychiatric disease from the Diagnostic and Statistical Manual of Mental Disorders (DSM)
5. History of surgical intervention for PD
6. History of certain malignancies
7. History of severe allergic anaphylactic reactions to any drug
8. Clinically significant baseline Electrocardiogram (ECG)
9. Orthostatic hypotension
10. HbA1c >7.0%

Exclusion criteria provided at time of registration:
1. Mini Mental State Examination (MMSE) score of less than 27
2. History or clinical features consistent with an atypical parkinsonian syndrome
3. Any significant non-PD central nervous system disorder
4. Any significant AXIS I psychiatric disease from the Diagnostic and Statistical Manual of Mental Disorders (DSM)
5. History of surgical intervention for PD
6. History of malignancy

7. History of severe allergic anaphylactic reactions to any drug
8. Clinically significant baseline Electrocardiogram (ECG)
9. Orthostatic hypotension

Date of first enrolment
31/12/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
MRC Clinical Sciences Centre
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Biogen Idec (USA)

Sponsor details
12 Cambridge Center
Bio 6, 6th Floor
Cambridge
United States of America
02142

Sponsor type
Industry

Website
http://www.biogenidec.com/

ROR
https://ror.org/02jqkb192

Funder(s)

Funder type
Industry

Funder Name
Biogen Idec (USA)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration