AN OPEN-LABEL STUDY IN HEALTHY MALE SUBJECTS TO ASSESS THE ABSORPTION, DISTRIBUTION, METABOLISM AND EXCRETION OF [14C]-LABELED BIA 9-1067 AND METABOLITES FOLLOWING A SINGLE-DOSE ORAL ADMINISTRATION

Published: 15-03-2011
Last updated: 28-04-2024

The purpose of the study is to investigate how quickly and to what extent the study drug is absorbed, distributed, metabolized (broken down) and eliminated from the body.

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

Summary

ID

NL-OMON35986

Source
ToetsingOnline

Brief title
BIA 9-1067 ADME study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Bial Portela & Ca.
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: BIA 9-1067, Parkinson's disease

Outcome measures

Primary outcome

- Radiokinetics

- Pharmacokinetics

Secondary outcome

n.a.

Study description

Background summary

The study drug is a new investigational compound that may eventually be used for the treatment of Parkinson's disease. The study drug is not registered as a drug but has been given to humans before.
The compound to be administered will be labeled with 14-Carbon (14C) and is thus radioactive. This enables the investigator to trace the compound in blood, expired air, urine and faeces. The safety and tolerability of the compound will also be evaluated.

Study objective

The purpose of the study is to investigate how quickly and to what extent the study drug is absorbed, distributed, metabolized (broken down) and eliminated from the body.

Study design

Design:
An open-label ADME study in six healthy male subjects receiving a 14C labeled, single oral dose of the study medication, containing approximately 3.33 MBq

radioacarbon.

Procedures and assessments
Screening and follow-up:
Screening: medical history, physical examination, clinical laboratory (blood and urine; a.o. alcohol and drug screen, HBsAg, anti HCV, anti-HIV 1/2 Clinical laboratory, vital signs (in triplicate at screening), vital signs and ECG. Upon admissoin vital signs, ECG and clinical laboratory (blood and urine; a.o. alcohol and drug screen) will be repeated.

Observation period:
one period in clinic from -17 h up to 240 h (Day 11) after drug administration on Day 1 followed by six 24 h hospitalizations on Days 14/15, 21/22, 28/29, 42/43, 56/57 and 77/78.

Blood sampling;
for total radioactivity in plasma and for bioanalysis of study drug + metabolites: pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 36, 48, 72, 120, 168, 240, 336, 504, 672, 1008, 1344, and 1848 h post-dose
for total radioactivity in whole blood : pre-dose and 1, 4, 12, 24, 48, 72, 120 and 168 h post-dose

Urine sampling:
for analysis of total radioactivity and for bioanalysis of study drug + metabolites: pre-dose and at intervals 0-6, 6-12, 12-24 h post-dose, followed by 24-h collections up to morning of Day 11 and 24 h collections on Days 14/15, 21/22, 28/29, 42/43, 56/57 and 77/78

Faeces sampling:
for analysis of total radioactivity and for bioanalysis of study drug + metabolites: all faeces up to morning of day 11 pooled as 24-hour fractions and stools before/on days 14/15, 21/22, 28/29, 42/43, 56/57 and 67/68, pooled as 24-hour fractions

Expired air:
for total radioactivity: pre-dose and 0.5, 1, 1.5, 2, 4, 8, 12, 24, 48, 72, 120, 168 and 240 h post-dose

Safety assessments:
adverse events: throughout study; vital signs: 2, 4 and 12 h post-dose and once daily on days 2, 4, 8 and 10; clinical laboratory in the morning of day 2

Bioanalysis:
analysis of study drug + metabolites samples using a validated method by sponsor
analysis of total radioactivity in plasma, whole blood, urine, faeces and expired air using a validated LCS method by PRA or using AMS by Xceleron (for

samples below LOQ of LSC; to be decided)

Intervention

Active stubstance: BIA 9-1067 and [14C] BIA 9-1067

Study burden and risks

In previous clinical studies with BIA 9-1067 in more than 600 healthy volunteers with single doses up to 1200 mg, once-daily doses up to 30 mg for 28 days or once-daily doses of 50 mg for 18 days, the most important adverse events reported were: somnolence, headache, dizziness and nausea.
The occurrence of known or other effects cannot be excluded.

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

healthy male subjects
Age: 18-55 years
BMI: 18.0 - 30.0 kg/m2

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study or in case of donating more than 1 liter of blood in the 10 months prior the start of this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2011
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

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	EUCTR2011-000298-30-NL
CCMO	NL36017.056.11