Single center, open label, non-randomized, non-placebo controlled study to investigate the pharmacokinetics, metabolic disposition, and mass balance after single administration of 20 mg [14C]neladenoson bialanate (oral solution) in healthy male subjects.

Published: 11-05-2017
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON44620

Source
ToetsingOnline

Brief title
Neladenoson bialanate mass balance study.

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Bayer AG
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: Chronic heart failure., Neladenoson bialanate.

Outcome measures

Primary outcome

Measure the cumulative amount (as well as the time course) of drug-related,

radioactive-labeled material excreted in urine and feces

following a single oral dose of 20 mg neladenoson bialanate blended with

radiolabeled [14C]neladenoson bialanate.

Secondary outcome

Assess the safety and tolerability of 20 mg neladenoson bialanate administered

as an oral solution in healthy male subjects.

Study description

Background summary

Neladenoson bialanate is a new investigational compound that may eventually be used for the treatment of chronic heart failure. Neladenoson bialanate is a so-called prodrug. This means that it is not active by itself, but it becomes active after it has been absorbed and processed by the body. The active compound is able to bind to a specific protein present on several cell types in the body, including cardiac muscle cells. It has been shown that due to the binding of the activated compound to the cardiac muscle cells, the condition

and the function of the cardiac muscle cells is
improved. Neladenoson bialanate is in development and is not registered as a drug but has been given to humans before.

Study objective

The purpose of the study is to investigate how quickly and to what extent neladenoson bialanate is absorbed, distributed, metabolized (broken down) and eliminated from the body (this is called pharmacokinetics). Neladenoson bialanate to be administered will be labeled with 14-Carbon (14C) and is thus radioactive (also called radiolabeled). In this way neladenoson bialanate can be traced in blood, urine and feces. It will also be investigated to what extent neladenoson bialanate is tolerated. This study will be performed in 6 healthy male volunteers. This study is not intended to improve the health, but is necessary for the further development of neladenoson bialanate.

Study design

The actual study will consist of 1 period during which the volunteers will stay in the clinical research center in Groningen (location Martini Hospital) for a maximum of 16 days (15 nights) followed by 1 day during which they will visit the clinical research center in Groningen for a short visit and one follow up visit. Day 1 is the day of administration of study compound. They are expected at the clinical research center at 11:00 h in the morning prior to the day of administration of the study compound. The volunteers will be required not to have consumed any food or drinks during the 10 hours prior to arrival in the clinical research center (with the exception of water). The participation to the entire study, from the pre-study screening until the follow-up, will depend on the amount of radioactivity left in urine and feces on Day 11. The amount of radioactivity in urine and feces will be measured from Day 1 onwards. If, from Day 11 onwards, the radioactivity levels in urine and feces are below the pre-defined levels, they will be allowed to leave the clinical research center. If the radioactivity levels in urine and feces are still above the pre-defined levels
on Day 11, they will have to stay in the clinical research center for 4 additional days at the maximum. This means that they will leave the clinical research center between Day 11 and Day 15. The volunteers should be aware that when the radioactivity levels are still above the pre-defined levels on Day 15, additional short periods on Day 21, Day 28, Day 35 and Day 42 (of 24 hours per period) may be scheduled for the collection of urine and/or feces until the radioactivity levels are below the pre-defined levels. On these additional days, they are expected at the clinical research center at 10:30 h in the morning.

They will return to the clinical research center on Day 29 for a short visit. The follow-up will take place 6 weeks after the day they received the study

compound. The appointment for the follow-up will be made as soon as it is known when the study will end for the volunteer. The participation in the entire study, from the pre-study screening will be a maximum of 10 weeks.

Intervention

Not applicable.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

Contacts

Public
Bayer AG

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DE
Scientific
Bayer AG

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Leverkusen 51368
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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
light skin (Caucasian)
18 - 55 years of age, inclusive
BMI 18.0 - 29.9 kilograms/meter2
smoking less than 10 cigarettes per day

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters 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):	06-06-2017
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	11-05-2017
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-05-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-08-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-09-2017
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
EudraCT	EUCTR2017-000297-11-NL
CCMO	NL61827.056.17