Open label, non-randomized, non-placebo controlled Phase 1 study to investigate the mass balance, pharmacokinetics and metabolic disposition of [14C]BAY 3283142 in healthy male participants.

Published: 01-08-2024
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To determine the mass balance and routes of excretion of total radioactivity after a single oral 10 mg dose of [14C]BAY 3283142 given as a solution. To quantify total radioactivity in plasma and whole blood

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56921

Source
ToetsingOnline

Brief title
BAY 3283142 Human Mass Balance Study

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
cardiorenal disease, chronic kidney disease

Health condition

chronic kidney disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: healthy volunteer, mass balance, phase 1

Outcome measures

Primary outcome

%AE,ur(0-tlast) and %AE,fec(0-tlast) (and amount in vomit as a percent of the dose, if applicable) of BAY 3283142 and its metabolites based on radioactivity excreted in urine and feces (as well as vomit, if applicable) as a percent of the dose to assess mass balance of total radioactivity. AUC*, Cmax of total radioactivity in plasma and whole blood

* if AUC cannot be determined reliably in all participants, AUC(0-tlast) will be used instead

Secondary outcome

Number of participants who experienced serious or non-serious TEAEs after administration of BAY 3283142

Study description

Background summary

sGC activators directly stimulate sGC to produce cGMP even under conditions of high oxidative stress, that lead to loss of the enzyme*s heme group and render it non-responsive towards stimulation with NO. NO deficiency, reduced sGC activity, and reduced cGMP levels have been implicated in the pathology and

progression of CKD.
It is anticipated that direct activation of sGC by BAY 3283142 under conditions of oxidative stress that are prevailing in CKD will reduce cardiovascular mortality and progression of kidney disease in patients suffering from CKD by reducing intraglomerular filtration pressure, albuminuria, and kidney fibrosis.
plaese see section 2.2 "background" of the clinical study protocol

Study objective

To determine the mass balance and routes of excretion of total radioactivity after a single oral 10 mg dose of [14C]BAY 3283142 given as a solution. To quantify total radioactivity in plasma and whole blood

Study design

single center, open label, non-randomized, non-placebo controlled, mass balance study.

Intervention

NA

Study burden and risks

please see section 2.3. "benefit/risk assessment" of the clinical study protocol version

Contacts

Public
Bayer

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Scientific
Bayer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Participant must be 18 to 55 years of age (both inclusive), at the time of signing the informed consent. Participants who are overtly healthy as determined by medical evaluation including medical history, physical examination, laboratory tests, and cardiac monitoring. Body mass index (BMI) within the range 18.0 and 29.9 kg/m2 (inclusive). Body weight equal or above 60 kg. Male.

Exclusion criteria

Pre-existing diseases for which it can be assumed that the absorption, distribution, metabolism, elimination, and effects of the study interventions will not be normal. Known or suspected liver disorders (e.g. chronic or acute hepatitis) or disorders of bile secretion/flow (cholestasis, also history of it) with the exception of Morbus Meulengracht. Acute diarrhea or constipation within 14 days before the first intake of study intervention. Regular use of medicines within the last 14 days before the first study intervention administration. Participant will be excluded when he participated in another study with a radiation burden of: greater than 0.1 and less or equal to 1.1 mSv within 1 year prior to screening; greater than 1.1 and less or equal to 2.1 mSv within 2 years prior to screening; greater than 2.1 and less or equal to 3.1 mSv within 3 years prior to screening, etc. (add 1 year per 1 mSv).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-10-2024
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	EnteroTracker® (ET-L-NS)
Registration:	No

Ethics review

Approved WMO

Date:	01-08-2024
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
Other	2024-510765-42-00
CCMO	NL86843.056.24