# Single-center, open-label, non-placebo-controlled, single-dose study in healthy male participants to determine the pharmacokinetics of BAY 1817080 oral solution (Part A) and to investigate the pharmacokinetics, metabolic disposition and mass balance of [14C]BAY 1817080 oral solution (Part B)

Published: 07-07-2020
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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON49615

**Source**
ToetsingOnline

**Brief title**
BAY 1817080 (P2X3 receptor antagonist) Mass Balance Study

### Condition

- Other condition

**Synonym**
chronic cough, Endometriosis

**Health condition**

chronic cough, Endometriosis

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** BAY 1817080, pharmacokinetics, radioactivity, safety

## Outcome measures

**Primary outcome**

Part A

• To assess the pharmacokinetics of a single oral dose of BAY 1817080 given as

a solution in healthy men.

Part B

• To determine the mass balance and route of excretion, to measure the

cumulative amount as well as the time course of drug-related, radiolabeled

material excreted in the urine and feces following a single oral dose of

[14C]BAY 1817080 given as a solution in healthy men.

• To quantify the total radioactivity in blood and plasma.

• To quantify unchanged BAY 1817080 in plasma.

**Secondary outcome**

Parts A and B

• To assess the safety and tolerability of a single oral dose of BAY 1817080

(Part A) and [14C]BAY 1817080 (Part B) given as a solution in healthy men.

# Study description

### Background summary

BAY 1817080 is a new compound that may potentially be used for the treatment of chronic cough and other conditions, such as endometriosis, neuropathic pain, and bladder disorders.

### Study objective

The purpose of this study is to investigate how quickly and to what extent BAY 1817080 is absorbed and eliminated from the body. BAY 1817080 will be labeled with Carbon-14 (14C) and is thus radioactive. In this way BAY 1817080 and its breakdown products (metabolites) can be traced in blood, urine and feces. It will also be investigated how safe BAY 1817080 is and how well it is tolerated when it is administered to healthy volunteers.

### Study design

Prior to receiving the study compound on the day of dosing (Day 1), the volunteer has to fast during the night for at least 10 hours. After this, the volunteer will be given a high fat, high calorie breakfast. This breakfast must be consumed entirely within 30 minutes. The volunteer will then receive 50 milligram (mg) of BAY 1817080 30 minutes after the start of the breakfast. BAY 1817080 will be given as an oral solution of 20 mL. After administration of the study compound, the vial will be rinsed twice with water, which the volunteer will also be required to drink. Thereafter, the volunteer is also required to drink an additional amount of water so that in total 240 mL of water is ingested.

### Intervention

Part A:
Day Description
-1 Entry in the research center
1 Administration of 50 mg BAY 1817080 and other procedures (see below)
2 and 3 Stay in the research center for blood samples and health checks
4 Leave the research center

Part B:
Day Description
-1 Entry in the research center
1 Administration of 50 mg 14C-labeled BAY 1817080 and other procedures (see below)
2-14 Stay in the research center for blood samples, health checks, and the collection of urine and feces
15 Leave the research center
22* 24-hour stay to collect urine and feces and to perform other procedures (see below)
29* 24-hour stay to collect urine and feces and to perform other procedures (see below)
36* 24-hour stay to collect urine and feces and to perform other procedures (see below)
43* 24-hour stay to collect urine and feces and to perform other procedures (see below)
* These visits are only needed if you did not meet the excretion criteria on the previous visit.

**Study burden and risks**

The study compound may cause side effects.
The so far observed side effect is taste disturbance. About 20% of participants of previous studies who were exposed to BAY 1817080 have reported taste perception-related changes. These were mostly mild in intensity, and none of the participants discontinued the study because of these changes. Changes were fully reversible after the end of treatment.

The following effects have been observed in single cases in humans, animal tests and/or in vitro laboratory tests (this means tests outside of the body) but it is not known yet whether it is related to BAY 1817080 and/or whether it is meaningful for patients. These potential study compound effects are:
• Increase in Antithrombin III activity
Antithrombin III is a protein which inhibits blood clotting. A slight increase in its activity has been observed after administration of BAY 1817080. Volunteers who received BAY 1817080 did not feel this change and it did not lead to any medical events like bleeding or bruising. The responsible doctor will regularly measure blood clotting parameters (laboratory tests) during the study.
• Potential decrease in heart rate and diastolic blood pressure
A small decrease in diastolic blood pressure (4-7 mmHg) and heart rate (5-11 beats per minute) was observed. Volunteers who received BAY 1817080 did not feel this change and it did not lead to any related medical events, such as dizziness or fainting. The responsible doctor will regularly measure blood pressure and heart rate during the study.
• Potential changes in liver function laboratory values
Based on laboratory tests there is a possibility of liver dysfunction due to

BAY 1817080. However, no liver dysfunction due to BAY 1817080 has been observed in humans. Your laboratory values will be assessed during the study. Results may trigger the need for additional laboratory tests.
• Potential irritation of skin and/or eye due to sunlight
Based on laboratory experiments, BAY 1817080 might cause skin and/or eye irritation after prolonged exposure to intensive sunlight. Your skin may become more sensitive to getting a sunburn. However, no such events occurred in clinical studies with BAY 1817080 thus far. As a precaution, you should avoid excessive exposure to sunlight during treatment with BAY 1817080. Please use conventional ultraviolet (UV) sunscreens, sunglasses and avoid prolonged sunbathing and use of solarium.

The study compound may also have side effects that are still unknown.

# Contacts

**Public**
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**Scientific**
Bayer AG

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Capable of giving signed informed consent as described in Appendix 10.1.4, which includes compliance with the requirements and restrictions listed in the ICF and in this protocol;
2. Ability to understand and follow study-related instructions;
3. Participant has signed the ICF before any study specific tests or procedures are done;
4. Healthy male participant;
5. Age: 18 to 65 years (inclusive) at the time of informed consent and first dose of study medication

For the complete overview see the protocol

## Exclusion criteria

1. Presence or history of clinically relevant cardiovascular, central nervous system (CNS), hepatic, hematopoietic disease, renal dysfunction, metabolic or endocrine dysfunction, serious allergy, asthma hypoxemia, hypertension, seizures, or allergic skin rash;
2. Known hypersensitivity to the study drugs (active substances or excipients of the preparations);
3. Known severe allergies, e.g., allergies to more than 3 allergens, allergies affecting the lower respiratory tract (e.g., allergic asthma), allergies requiring therapy with corticosteroids or significant non-allergic drug reactions;
4. Febrile illness within 1 week before study drug administration;
5. Current or recent (within 6 months) gastrointestinal disease that would be expected to influence the absorption of drugs (i.e., a history of malabsorption, esophageal reflux, peptic ulcer disease, erosive esophagitis, frequent occurrence of heartburn [more than once per week], or any gastrointestinal surgical intervention [e.g. cholecystectomy]);

For the complete overview see the protocol

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |

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| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 05-08-2020 |
| Enrollment: | 14 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 07-07-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 27-07-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 30-10-2020 |
| 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 | EUCTR2020-000519-54-NL |
| CCMO | NL74231.056.20 |

# Study results

Date completed: 30-10-2020

Results posted: 07-09-2021

**First publication**
23-07-2021