A phase 1, open-label, randomized, 2-period, 2-sequence, crossover study to evaluate the bioequivalence of Bosutinib pediatric capsule and the commercial tablet formulations in healthy participants under fed condition

Published: 19-08-2020
Last updated: 08-04-2024

The purpose of this study is to investigate how quickly and to what extent bosutinib is absorbed and eliminated from the body (this is called pharmacokinetics). The pharmacokinetics of bosutinib administered as a capsule will be compared to the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON49458

Source
ToetsingOnline

Brief title
Bioequivalence of Bosutinib Capsule Relative to Tablet

Condition

- Leukaemias

Synonym
chronic myeloid leukemia

Research involving

Human

Sponsors and support

Primary sponsor: Pfizer, Inc.
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Bioequivalence, Bosutinib

Outcome measures

Primary outcome

To assess the bioequivalence of bosutinib pediatric capsule formulation (Test) to the commercial tablet formulation (Reference) at a 100 mg dose under fed condition in adult healthy participants.

Secondary outcome

To evaluate the PK of bosutinib when administered as a capsule and tablet formulation to healthy participants under fed condition.

To evaluate the safety and tolerability of bosutinib when administered as a capsule and tablet formulation to healthy participants under fed condition.

Study description

Background summary

Bosutinib is a compound that is used for the treatment of chronic myeloid leukemia (CML). The tablet formulation of bosutinib is already approved for the treatment of CML in the Europe (EU) and the USA. The Sponsor is developing a capsule formulation, which is more appropriate for the treatment of certain types of patients (eg, children).

Study objective

The purpose of this study is to investigate how quickly and to what extent

bosutinib is absorbed and eliminated from the body (this is called pharmacokinetics). The pharmacokinetics of bosutinib administered as a capsule will be compared to the pharmacokinetics of bosutinib administered as a tablet.

Study design

The volunteer will receive bosutinib once as an oral tablet and once as an oral capsule. Bosutinib will be ingested with approximately 240 milliliters (mL) of (tap) water. In both administrations, the dose will be 100 mg.

The actual study will consist of 2 periods. During each period, the volunteer will stay in the research center for 6 days (5 nights).

Intervention

N/A

Study burden and risks

The following side effects have been observed in people taking bosutinib:

Very frequently observed (in more than 1 in 10 people):
• Abdominal pain
• Appetite decrease
• Back pain
• Common cold (nasopharyngitis)
• Diarrhea
• Difficulty breathing (dyspnea)
• Dizziness
• Fatigue
• Fever (pyrexia)
• Headache (cephalgia)
• Joint pain (arthralgia)
• Lipase elevation (a pancreatic enzyme)
• Liver enzyme increase (ALT, AST)
• Loss of strength (asthenia)
• Nausea
• Platelet decrease (thrombocytopenia)
• Rash
• Red blood cell decrease (anemia)
• Respiratory tract infection (including upper lower, and viral respiratory tract infections)
• Swelling (oedema) including face, arms, legs, and localized swelling
• Vomiting
• White blood cell (neutrophil) decrease (neutropenia)

Contacts

Public
Pfizer, Inc.

East 42nd Street 235
New York NY 10017
US
Scientific
Pfizer, Inc.

East 42nd Street 235
New York NY 10017
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Female participants of non-childbearing potential and/or male participants must be 18 to 54 years of age, inclusive, at the time of signing the ICD.
2. Male and female participants who are overtly healthy as determined by medical evaluation including a detailed medical history, complete physical examination, vital signs which include BP and pulse rate measurement, clinical laboratory tests, and ECG.
3. Participants who are willing and able to comply with all scheduled visits, treatment plan, laboratory tests, lifestyle considerations, and other study procedures.
4. BMI of 17.5 to 30.0 kg/m2; and a total body weight >50 kg (110 lb).
5. Capable of giving signed informed consent as described in Appendix 1, which includes compliance with the requirements and restrictions listed in the ICD

and in this protocol.

Exclusion criteria

1. Evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, neurological, dermatological, or allergic disease (including drug allergies, but excluding untreated, asymptomatic, seasonal allergies at the time of dosing).
2. Any condition possibly affecting drug absorption (eg, gastrectomy, cholecystectomy).
3. History of HIV infection, hepatitis B, or hepatitis C; positive testing for HIV, HBsAg, HBcAb or HCVAb. As an exception, a positive HBsAb as a result of participant vaccination is permissible.
4. Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk
PF-05208763 of study participation or, in the investigator*s judgment, make the participant inappropriate for the study.
5. A history of hypersensitivity to the active compounds or to any inactive ingredients (excipients) contained in the formulations.

For complete overview see the protocol

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):	15-09-2020
Enrollment:	66
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N/A
Generic name:	Bosutinib
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-08-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-09-2020
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	EUCTR2020-002782-34-NL
CCMO	NL74763.056.20