A phase 1, open-label, 2-period, fixed sequence, study to investigate the absorption, metabolism and excretion of 14C-PF-06650833 and to assess the absolute bioavailability and fraction absorbed of PF-06650833 in healthy male subjects using a 14C-microdose approach.

Published: 13-11-2017
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The purpose of this study is to investigate how quickly and to what extent PF-06650833 is absorbed, distributed, metabolized (broken down) and eliminated from the body (this is called pharmacokinetics). PF-06650833 is not registered as a drug, but...

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

Summary

ID

NL-OMON44374

Source
ToetsingOnline

Brief title
A phase 1 study to investigate ADME and BA of 14C-PF-06650833.

Condition

- Autoimmune disorders

Synonym
Rheumatoid Arthritis; autoimmune disease.

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer, inc.
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: PF-06650833, reumatoïde artritis (RA)

Outcome measures

Primary outcome

To characterize the rates and extent of excretion of total radioactivity in

urine and feces after single oral administration of 14C-PF-06650833-LR.

Secondary outcome

To identify the metabolites of PF-06650833 in plasma, urine and feces, if

possible.

To determine the pharmacokinetics of PF-06650833 following IV and oral

administration of PF-06650833.

To determine renal clearance of PF-06650833.

To determine the safety and tolerability of PF-06650833 following simultaneous

oral/IV administration.

Study description

Background summary

PF-06650833 is a new compound that may eventually be used for the treatment of

Rheumatoid Arthritis (RA), which is an autoimmune disease. PF-06650833 is a so-called interleukin-1 receptor-associated kinase 4 (IRAK 4) inhibitor. This means that PF-06650833 is able to inhibit the activity of certain enzymes inside cells, including white blood cells. This will ultimately lead to the inhibition of the production of inflammatory proteins by these white blood cells. As a result, there may be a decrease in inflammatory processes that are characteristic for RA.

Study objective

The purpose of this study is to investigate how quickly and to what extent PF-06650833 is absorbed, distributed, metabolized (broken down) and eliminated from the body (this is called pharmacokinetics). PF-06650833 is not registered as a drug, but has been given to humans before.

Part of the PF-06650833 to be administered will be labeled with 14 Carbon (14C) and is thus radioactive (also called radiolabeled). In this way PF-06650833 can be traced in blood, urine and feces. The amount of radioactivity will be negligible. It will also be investigated how PF-06650833 is tolerated. In addition, the taste of PF-06650833 will be investigated.

Study design

The study consists of 2 periods. In the first period (Period A) the volunteers will receive 300 mg 14C radiolabeled PF-06650833 as an oral solution with tap water to a volume of 240 mL. In the second period (Period B) they will receive 300 mg unlabeled PF-06650833 as an oral solution in tap water to a volume of 240 mL. Two hours later they will receive 10 mL 14C radiolabeled PF-06650833 as an intravenous infusion over 5 minutes.
When PF-06650833 is administered, they should have fasted for at least 8 hours (no eating and drinking). Also after administration of the study compound, they will be required to fast for 4 additional hours. Then they will be served lunch. During fasting the volunteers are allowed to drink water, except during 1 hour before and 1 hour after administration of the study compound (for Period B: after the intravenous infusion).

Intervention

Not applicable.

Study burden and risks

Pain, minor bleeding, bruises and possibly an infection.

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

healthy male subjects
18 - 55 years of age
BMI 17.5 - 30.5 kilograms/meter2
Weight >50 kg

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2017
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	28-11-2017
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	EUCTR2017-002044-32-NL
CCMO	NL63629.056.17