A Phase 1, Open-Label, Non-Randomized, 2-Period, Fixed Sequence Study to Investigate the Absorption, Distribution, Metabolism and Excretion of [14c-Pf-06700841] and to Assess the Absolute Bioavailability and Fraction Absorbed of Pf-06700841 in Healthy Male Subjects using a 14C-Microtracer Approach

Published: 05-11-2018
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The purpose of this study is to investigate how safe the new compound PF-06700841 is and how well it is tolerated when it is administered to healthy volunteers. PF-06700841 has been administered to humans before. It will also be investigated how…

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

Summary

ID

NL-OMON45995

Source
ToetsingOnline

Brief title
PF-06700841 ADME microtracer study

Condition

- Autoimmune disorders

Synonym
Psoriasis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ADME, Microtracer, Open-label, PF-06700841

Outcome measures

Primary outcome

To characterize the rate and extent of radioactivity excretion of PF-06700841

and drug related material.

Secondary outcome

To identify the metabolites of PF-06700841 in plasma, urine and feces, if

possible.

To determine the pharmacokinetics of PF-06700841 following oral administration

of PF-06700841 and 14C-PF-06700841 following IV administration of

14C-PF-06700841, and of total 14C in plasma following oral 14C-PF-06700841.

To determine the oral absolute bioavailability (F) of PF-06700841 in solution

following single dose administration under fasted condition.

To determine the fraction of PF-06700841 dose absorbed (Fa).

To determine the safety and tolerability of PF-06700841 following simultaneous

oral/IV administration.

Study description

Background summary

PF-06700841 is a new compound that may eventually be used for the treatment of autoimmune and inflammatory diseases, such as psoriasis and inflammatory bowel disease.

PF-06700841 is a, so-called, dual TYK2/JAK1 (tyrosine kinase 2 / janus kinase 1) inhibitor. TYK2 and JAK1 are each involved in different aspects of the immune response. PF-06700841 suppresses both TYK2 and JAK1, and it is thought that by suppressing multiple aspects of the immune response PF-06700841 will be effective in treating various inflammatory diseases, such as psoriasis.

Study objective

The purpose of this study is to investigate how safe the new compound PF-06700841 is and how well it is tolerated when it is administered to healthy volunteers. PF-06700841 has been administered to humans before.

It will also be investigated how quickly and to what extent PF-06700841 is absorbed and eliminated from the body . PF-06700841 will be labelled with 14 Carbon (14C) and is thus radioactive.

In addition, the taste of the oral solution of PF-06700841 will be assessed.

Study design

The actual study will consist of 2 periods. During the first period the subjects will stay in the research center for a minimum of 6 days (5 nights) and maximum of 15 days (14 nights). During the second period the subjects will stay in the research center for a minimum of 6 days (5 nights) and a maximum of 8 days (7 nights). The second period will start 16 days after administration of the study compound in the first period.

Because of logistical reasons (discharge will be based on outsourced laboratory results) the chance is very high the subjects have to stay at the research center for a minimum for at least 8 days (7 nights) in both periods.

In each period, Day 1 is the first day of administration of the study compound.

In both periods the subjects are expected at the research center at 14:00 h in the afternoon prior to the day of administration of the study compound (Day -1).

In the first period the subjects will be given 60 mg 14C (radiolabeled) PF-06700841 as a drink of 240 milliliters (mL). the subjects will have to fill out a taste assessment questionnaire immediately after drinking the solution with the study compound, and again after 5, 10 and 20 minutes.

In the second period the subjects will be given 60 mg (non-radiolabeled) PF-06700841 as a drink of 240 mL, similar as in period 1. About 1 hour after the drink, the subjects will receive 30 µg 14C PF-06700841 and as an intravenous infusion (solution of the compound that will be administered directly in a blood vessel). The infusion will last about 5 minutes.

Intervention

In the first period the subjects will be given 60 mg 14C (radiolabeled) PF-06700841 as a drink of 240 milliliters (mL).

In the second period the subjects will be given 60 mg (non-radiolabeled) PF-06700841 as a drink of 240 mL, similar as in period 1. About 1 hour after the drink, the subjects will receive 30 µg 14C PF-06700841 and as an intravenous infusion (solution of the compound that will be administered directly in a blood vessel).

Study burden and risks

Drawing blood and/or insertion of the indwelling cannula may be painful or cause some bruising.

In total, we will take about 477 mL of blood. This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time.

To make a heart tracing, electrodes (small, plastic patches) will be pasted at specific locations on the arms and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Contacts

Public
Pfizer, Inc.

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US
Scientific
Pfizer, Inc.

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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Healthy male subjects who, at the time of screening, are between the ages of 18 and 55 years, inclusive. Healthy is defined as no clinically relevant abnormalities identified by a detailed medical history, full physical examination, including BP and pulse rate (PR) measurement, 12-lead electrocardiogram (ECG), or clinical laboratory tests.;2.Body mass index (BMI) of 17.5 to 30.5 kg/m2; and a total body weight >50 kg (110 lbs).;3.Evidence of a personally signed and dated informed consent document indicating that the subject has been informed of all pertinent aspects of the study.;4.Subjects who are willing and able to comply with study confinement period, scheduled visits, treatment plan, laboratory tests, contraceptive requirements and other study procedures.

Exclusion criteria

1.Evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, neurologic, or allergic disease (including drug allergies, but excluding untreated, asymptomatic, seasonal allergies).;2.Any clinically significant malabsorption condition (eg, gastrectomy, bowel resection).;3.Inability to have at least one bowel movement every 2 days on average.;4.A positive urine drug screen for drugs

of abuse or recreational drugs.

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):	10-12-2018
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-11-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-10-2019
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	EUCTR2018-002403-34-NL
CCMO	NL67100.056.18