A phase 1, open-label, non-randomized, 2-period, fixed sequence study to investigate the absorption, metabolism and excretion of [14C-PF-04965842] and to assess the absolute bioavailability and fraction absorbed of PF-04965842 in healthy male subjects using a 14C-microtracer approach.

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

Summary

ID

NL-OMON45258

Source
ToetsingOnline

Brief title
A phase 1 study to investigate ADME and BA of [14C-PF-04965842].

Condition

- Other condition
- Autoimmune disorders

Synonym
auto-immune disease, eczema

Health condition

eczeem

Research involving
Human

Sponsors and support

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

Intervention

Keyword: eczema (atopic dermatitis), JAK1 inhibitor, PF 04965842, systemic lupus erythematosus (SLE)

Outcome measures

Primary outcome

To characterize the rate and extent of radioactivity excretion of PF-04965842

and drug related material.

Secondary outcome

To identify the metabolites of PF-04965842 in plasma, urine and feces, if

possible.

To determine the pharmacokinetics of PF-04965842 following IV and oral

administration of PF-04965842.

To determine the oral absolute bioavailability (F) of PF-04965842 following

single dose administration under fasted condition.

To determine the fraction of PF-04965842 dose absorbed (Fa).

To determine the safety and tolerability of PF-04965842 following simultaneous

oral/IV administration.

Study description

Background summary

PF 04965842 is a new investigational compound that may eventually be used for the treatment of eczema (atopic dermatitis) and systemic lupus erythematosus (SLE), which is an autoimmune disease. PF 04965842 is a so-called Janus kinase 1 (JAK1) inhibitor. This means that PF 04965842 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 eczema and SLE. PF 04965842 is in development and is not registered as a drug but has been given to humans before.

Study objective

The purpose of the study is to investigate how quickly and to what extent PF 04965842 is absorbed, distributed, metabolized (broken down) and eliminated from the body (this is called pharmacokinetics). A small part of the PF 04965842 to be administered will be labeled with 14 Carbon (14C) and is thus radioactive (also called radiolabeled). In this way PF 04965842 can be traced in blood, urine and feces. The amount of radioactivity is negligible as explained in Section *How much radiation will I be exposed to in this study?*. It will also be investigated to what extent PF 049658421234 is tolerated. In addition, the taste of PF 04965842 will be investigated.

This study will be performed in approximately 6 healthy male volunteers.

Study design

The actual study will consist of 2 periods. During the first period the volunteers will stay in the clinical research center in Groningen (location UMCG Hospital) for a minimum of 8 days (7 nights) and a maximum of 15 days (14 nights). During the second period they will stay in the clinical research center in Groningen (also at the location UMCG) for 8 days (7 nights). They will be contacted by phone for a follow-up at approximately 28 days after they have received the study compound for the last time. The time interval between the days on which they will receive the study compound is 10 to 17 days, depending on the day they will leave the clinical research center.

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

periods, the volunteers are expected at the clinical research center at 14:00 h in the afternoon prior to the day of administration of the study compound.They will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).

They will leave the clinical research center between Day 7 and Day 14 in the first period and on Day 7 in the second period. If in the first period, from Day 6 onwards, the radioactivity levels in urine and feces are below the pre-defined levels, they will be allowed to leave the clinical research center earlier (thus before Day 14 in the first period).

They will be contacted by phone on Day 28 of the second period for a follow-up.

The participation to the entire study, from the pre-study screening until the follow-up phone call will be a maximum of 12 weeks.

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, inclusive
BMI 17.5 - 30.5 kilograms/meter2, inclusive

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):	10-07-2017
Enrollment:	6

Type:	Actual

Ethics review

Approved WMO Date:	12-06-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2017
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	EUCTR2017-000461-73-NL
CCMO	NL61396.056.17