A PHASE 1, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, SINGLE-DOSE ESCALATION, MULTIPLE-DOSE ESCALATION, AND FOOD EFFECT STUDY OF FLX475 IN HEALTHY MALE AND FEMALE SUBJECTS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON44307

Source
ToetsingOnline

Brief title
FLX475 SAD, MAD and FE Study.

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Cancer Treatment

Research involving

Human

Sponsors and support

Primary sponsor: FLX Bio, Inc.
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Cancer Treatment, FLX475

Outcome measures

Primary outcome

Part A: To evaluate the safety and tolerability of single oral ascending doses

of FLX475 administered to healthy male and female subjects

Part B: To evaluate safety and tolerability of multiple oral ascending doses of

FLX475 administered for 14 days to healthy male and female subjects

Secondary outcome

Part A:

- To evaluate the pharmacokinetics (PK) of FLX475 following administration of

single oral ascending doses of FLX475 administered to healthy male and female

subjects

- To assess the food effect (FE) on the PK of FLX475 following administration

of a single oral dose of FLX475 administered to healthy male and female

subjects

- To compare the PK of an alternative drug product formulation of FLX475

following administration of a single oral dose administered to healthy male and

female subjects

Part B:

- To evaluate the PK of FLX475 following administration of multiple oral

ascending doses of FLX475 administered to healthy male and female subjects

Study description

Background summary

FLX475 is a new compound that may eventually be used for the treatment of cancer. The immune system that protects the body from foreign invaders, like viruses and bacteria, can also recognize and kill tumor cells. The immune response is tightly controlled to prevent it from running unchecked and attacking the body*s own cells, resulting in autoimmunity. However, these control mechanisms can also interfere with the immune response against tumor cells.

Treatments that act on interfering with these control mechanisms have resulted in meaningful responses of the immune system attacking tumors. However only a small group of patients showed a long-lasting response to these treatments.

FLX475 works via another mechanism in enhancing the immune response against tumors. Specific immune cells, called regulatory T-cells, are recruited into tumors, and thus suppress the immune response against tumor cells. These T-cells are recruited into the tumor by small
signal proteins called chemokines which are produced by the tumor.

FLX475 reduces the possibility of these chemokines to bind to the T-cells and so prevents these T-cells from being recruited by the tumor. This way FLX475 allows the immune system to elicit an antitumor response.

Study objective

The purpose of this study is to investigate how safe the new compound FLX475 is when it is administered to healthy subjects. FLX475 has not been administered to humans before. It has been previously tested in the laboratory and on animals. FLX475 will be tested at various dose levels.

It will also be investigated how quickly and to what extent FLX475 is absorbed and eliminated from the body. This is called pharmacokinetics. Also, this study will investigate how food affects the pharmacokinetics of an alternative formulation of FLX475. In addition, the effect of FLX475 on the body will be investigated (this is called pharmacodynamics).

The effects of FLX475 will be compared to the effects of a placebo. A placebo is a medicine without any active ingredient. It is a *fake* medicine.

Study design

This study will be performed in up to 104 healthy volunteers divided over Part A and Part B.

Part A will be performed in up to 56 healthy volunteers divided over up to 7 groups of 8 healthy male of female volunteers. In Part A increasing doses of FLX475 or placebo will be investigated when administered as single doses. The effect of giving FLX475 shortly after breakfast, as well as the effect of an alternative formulation of FLX475 will also be investigated.

Before the study the volunteers will undergo a pre-study screening during which they will be subjected to a number of medical examinations.
Similar examinations will be performed after the study at the follow-up visit.
This pre-study screening may be done up to 28 days before Day 1.
they will stay in the clinical research center for one period of 4 days (4 nights) from Day -1 to Day 4 (volunteers in group A4 have 3 periods).

The volunteers are expected at the clinical research center at 14:00 h in the afternoon of Day -1. 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). The study doctor must be informed if any doses of the own oral contraceptive were missed during the month prior to participating in the study. They will leave the clinical research center on Day 4. An additional visit to the research center will be on Day 7. The follow-up visit will take place on day 16 +/- Day 1. The appointment for the follow-up visit will be made with you during the study. The participation in the entire study, from the pre-study screening until the follow-up visit, will be a maximum of 7 weeks (for group A1, A2, A3, A5, A6, A7) and 12 weeks (for group A4).

In Part B will be performed in up to 48 healthy volunteers divided over a maximum of 6 groups of 8 healthy male of female volunteers. In Part B increasing doses of FLX475 or placebo will be investigated when administered once daily for 14 days.

Before the study the volunteers will undergo a pre-study screening during which they will be subjected to a number of medical examinations.
Similar examinations will be performed after the study at the follow-up visit.
This pre-study screening may be done up to 28 days before Day 1.
they will stay in the clinical research center for one period of 18 days (17 nights) from Day -1 to Day 17.

The volunteers are expected at the clinical research center at 14:00 h in the

afternoon of Day -1. 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). The study doctor must be informed if any doses of the own oral contraceptive were missed during the month prior to participating in the study. They will leave the clinical research center on Day 17. An additional visit to the research center will be on Day 20.The follow-up visit will take place on day 29 +/- Day 1. The appointment for the follow-up visit will be made with you during the study. The participation in the entire study, from the pre-study screening until the follow-up visit, will be a maximum of 9 weeks.

Intervention

n.a.

Study burden and risks

Infection, pain, minor bleedings, bruises, possibly an infection.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- healthy male or female subjects
- 18-55 yrs, inclusive
- BMI: 18.0-30.0 kg/m2, inclusive
- non-smoking

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
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2017
Enrollment:	104

Type:	Actual

Ethics review

Approved WMO Date:	06-11-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-11-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-02-2018
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	EUCTR2017□003952□22-NL
CCMO	NL63737.056.17