A phase 1, randomized, placebo-controlled study to assess the safety and pharmacokinetics of multiple ascending dose regimens of TP-6076.

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

Summary

ID

NL-OMON45496

Source
ToetsingOnline

Brief title
TP-6076 MAD study

Condition

- Other condition

Synonym
Infections.

Health condition

Infecties.

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Infections with bacteria for which other antibiotics don□t work anymore., TP-6076

Outcome measures

Primary outcome

To assess the safety and tolerability of multiple dose regimens of TP-6076.

Secondary outcome

To determine the plasma pharmacokinetic (PK) profile for TP-6076, its carbon-4

(C-4) epimer TP-5589, and degradation products TP-2847 and TP-5031 following

multiple doses.

To determine the urinary excretion of TP-6076 following multiple doses.

Study description

Background summary

TP-6076 is a new investigational compound that may eventually be used for the treatment of infections with bacteria for which other antibiotics don*t work anymore. TP-6076 is a tetracycline. Tetracyclines are a group of antibiotics that were used a lot for specific infections (urinary tract, airway and intestinal infections), but that can be used less and less as a result of the development of resistance in the bacteria. Tetracyclines like TP-6076 block the function of certain enzymes in the bacteria.TP-6076 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 safe TP-6076 is and how well

TP-6076 is tolerated. It will also be investigated how quickly and to what extent TP-6076 is absorbed and eliminated from the body (this is called pharmacokinetics). This study will be performed in 56 healthy male and female volunteers, divided over a maximum of 7 groups.

Study design

The actual study will consist of 1 period during which the volunteer will stay in the clinical research center in Groningen (location Martini Hospital) for 12 days (11 nights). They are expected at the clinical research center at 14:00 h in the afternoon prior to the first 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). The volunteer will leave the clinical research center on Day 11 (Day 1 is the first day of administration of the study compound). The follow-up visit will take place between Day 13 and Day 16 of the study. The appointment for the follow-up visit will be made during the study. The participation to the entire study, from the pre-study screening until the follow-up visit, will be a maximum of 46 days (approximately 6.5 weeks).

During the study the volunteer will receive TP-6076 or placebo as an iv infusion of 30 minutes (in groups 1-3) or 60 minutes (group 4) under fasted conditions. This means that they are not allowed to eat for at least 10 hours before administration of the study compound. During fasting they are allowed to drink water with the exception of 2 hours prior to until 1 hour after administration of the study compound. They will receive a breakfast 30 minutes after the end of each iv infusion.

Intervention

Group 1; Day 1 to 7 TP-6076 6.0 mg or placebo; once daily
Group 2; Day 1 to 7 TP-6076 20.0 mg or placebo; once daily
Group 3; Day 1 to 7 TP-6076 40.0 mg or placebo; once daily
Group 4; Day 1 to 7 TP-6076 60.0 mg or placebo; once daily
Group 5; Day 1 TP-6076 40.0 mg or placebo; once daily
Group 5; Day 1 to 7 TP-6076 20.0 mg or placebo; twice daily

Treatment for Group 6 and 7 will be decided based on the results from previous groups. You will be informed about the amount and frequency of the study compound administration after you entered the clinical research center. The treatment will be within the ranges as described below.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

The study compound is a tetracycline. The following adverse effects are known for tetracyclines, although they are not reported very often:
Nausea, vomiting, photosensitivity (therefore you are not allowed to stay in the sun), increased intracranial pressure, pancreatitis, allergic reactions, abdominal pain, headache, loss of appetite, visual changes, increased frequency of urination or amount of urine, increased thirst, unusual tiredness or weakness, pigmentation (darker color or discoloration) of skin, bone and teeth, cramps or burning of the stomach, diarrhea, change in stool color, sore mouth or tongue, dizziness, light-headedness and unsteadiness, , and pain, swelling and irritation at the infusion site.

Contacts

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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
18-55 years, inclusive
BMI 18.0-35.0 kilogram/meter2
Weight between 50 (female) and 60 (male) and 105 kilograms, inclusive
Non smokers

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):	29-03-2017
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-03-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-04-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-04-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-06-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-09-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-09-2017
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	EUCTR2017-000509-19-NL
CCMO	NL61213.056.17