A randomized, double-blind, placebo-controlled study of the safety, tolerability, and pharmacokinetics of single and multiple ascending oral doses of CFTX-1554 in healthy subjects, with comparison of intake of CFTX-1554 as liquid formulation and as capsule, and after a high-fat breakfast versus fasted.

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In this study we will investigate how safe the new compound CFTX-1554 is and how well it is tolerated when it is used by healthy participants.We also investigate how quickly and to what extent CFTX-1554 is absorbed, distributed, metabolized, and...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51471

Source
ToetsingOnline

Brief title
SAD / MAD/ FE HV

Condition

- Other condition
- Neurological disorders NEC

Synonym
nerve pain, peripheral neuropathic pain

Health condition

nerve pain (peripheral neuropathic pain)

Research involving
Human

Sponsors and support

Primary sponsor: Confo Therapeutics
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: CFTX-1554, Healty Subjects, Pharmacokinetics, Safety

Outcome measures

Primary outcome

To assess the safety and tolerability of single and multiple ascending oral

doses of CFTX-1554 in healthy subjects

Secondary outcome

To assess the PK of single and multiple ascending oral doses of CFTX-1554 in

healthy subjects, including the exposure after intake with food (high-fat

breakfast) in comparison with intake fasted, and after intake as capsule in

comparison with intake as liquid formulation (1 dose level only)

Exploratory

To explore the effect of AT2R inhibition on the capsaicin-induced dermal blood

flow response in healthy subjects using 3 single-dose levels (low-, mid-, and

high-dose) of CFTX-1554

Study description

Background summary

CFTX-1554 is a new compound that may potentially be used for the treatment of nerve pain (peripheral neuropathic pain). Neuropathic (nerve) pain is a chronic condition caused by nerve damage, which can result from conditions like diabetes and herpes infection. Current treatments have limited effectiveness and significant side effects. CFTX-1554 is a new potential treatment for this condition, which acts in a different way from the current treatments by blocking a different pain pathway called the AT2 receptor.

Study objective

In this study we will investigate how safe the new compound CFTX-1554 is and how well it is tolerated when it is used by healthy participants.

We also investigate how quickly and to what extent CFTX-1554 is absorbed, distributed, metabolized, and eliminated from the body. In addition, we look at the effect of CFTX-1554 on the body.

CFTX-1554 has not been used by humans before. It has been extensively tested in the laboratory and on animals. CFTX-1554 will be tested at various dose levels.

We will compare the effects of CFTX-1554 with the effects of a placebo.

For this study we are looking for 107 healthy male or female participants. The study will consist of 3 parts, Part A, Part B and Part C.

Study design

Part A:
The study will take a maximum of 5 weeks from the screening until the follow-up visit.
For the study it is necessary that the volunteer stays in the research center for 1 period of 4 days (3 nights).
Between Day 8 and Day 13 the volunteers health will be checked for the last time. The appointment for this follow up visit will be made during the study.

Part A (Group A5 only):
The study will take a maximum of 8 weeks from the screening until the follow-up visit.
For the study it is necessary that the volunteer stays in the research center for a maximum of 4 periods of 4 days (3 nights)
Between Day 8 and Day 13 of the fourth period the volunteers health will be

checked for the last time. The appointment for this follow up visit will be made during the study.

Part B:
The study will take a maximum of 7 weeks from the screening until the follow-up visit.
For the study it is necessary that the volunteer stays in the research center for 1 period of 17 days (16 nights).
Between Day 21 and Day 26 the volunteers health will be checked for the last time. The appointment for this follow up visit will be made during the study.

Part C:
The study will take a maximum of 9 weeks from the screening until the follow-up visit.
For the study it is necessary that the volunteer stays in the research center for 4 periods of 4 days (3 nights).
Between Day 8 and Day 13 of the fourth period the volunteers health will be checked for the last time. The appointment for this follow up visit will be made during the study.

Intervention

Part A:
The planned dose levels for the study are as follows:
Group Day Treatment* How often
A1 1 CFTX-1554 30 mg* (3 participants) or placebo (2 participants) once
A2 1 CFTX-1554 90 mg* (3 participants) or placebo (2 participants) once
A3 1 CFTX-1554 250 mg* (6 participants) or placebo (2 participants) once
A4 1 CFTX-1554 500 mg* (6 participants) or placebo (2 participants) once
A5 1 CFTX-1554 1000 mg* (6 participants) or placebo (2 participants) once
A6 1 CFTX-1554 1500 mg* (6 participants) or placebo (2 participants) once
A7 1 CFTX-1554 2000 mg* (6 participants) or placebo (2 participants) once

* In case the dose level will be lower or higher than planned, the volunteer will be informed verbally.

Part A (Group A5 only):
The planned dose levels for the study are as follows:
Group Day Treatment How often Formulation Food status
A6 1 A: CFTX-1554 1000 mg (6 participants) or placebo (2 participants) once Liquid Fasted
1 B: CFTX-1554 1000 mg (6 participants) once Liquid High-fat breakfast
1 C: CFTX-1554 1000 mg (6 participants) once Capsule Fasted
1 D: CFTX-1554 1000 mg (6 participants) once Capsule High-fat breakfast

Part B:
The planned dose levels for the study are as follows:

Group Day Treatment How often
B1 1-14 CFTX-1554 xx mg* (8 participants) or placebo (2 participants) once daily or twice daily for 14 days
B2 1-14 CFTX-1554 xx mg* (8 participants) or placebo (2 participants) once daily or twice daily for 14 days
B3 1-14 CFTX-1554 xx mg* (8 participants) or placebo (2 participants) once daily or twice daily for 14 days
B4 1-14 CFTX-1554 xx mg* (8 participants) or placebo (2 participants) once daily or twice daily for 14 days

* The doses are not known yet and will be based on the results of Part A. The volunteer will be informed verbally which dose the volunteer will receive.

Part C:
Group C1 has 4 periodes. On day 1 of each period a single dose of xx CFTX-1554 will be administered.
* The doses are not known yet and will be based on the results of Part A. The volunteer will be informed verbally which dose the volunteer will receive.

Study burden and risks

Possible side effects:
The study compound may cause side effects.

As CFTX-1554 will be administered to humans for the first time in this study, side effects of CFTX-1554 in humans are not known yet. CFTX-1554 has been studied extensively in the laboratory and in animals. A 28-day study in rats showed mild enlargement of liver cells and a 28-day study in dogs showed salivation, vomiting, diarrhea and an increase in blood pressure. These side effects mainly occurred at the highest doses. These side effects also stopped after the administration of the study compound was stopped.

The study compound may also have (serious) side effects that are still unknown. In addition to unknown side effects, there is a (small) chance that an allergic reaction will occur.

Possible discomforts:
Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula (a tube in a vein in the arm) can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and bleeding in the environment (bruising) of the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, seating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, we will take about (Part A) 99 (Part A, Group A5 only) 342 (Group B)

292 milliliters (mL) of blood from the volunteer. This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time. If the investigator thinks it is necessary for the safety of a participant, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

Heart tracing
To make a heart tracing, electrodes (small, plastic patches) will be placed on the volunteers arms, chest and legs. To monitor your heart rate, electrodes (small, plastic patches) will be placed on the chest and abdomen. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Fasting/Meals (Part A, Group A5 only)
If the volunteer has to fast for a prolonged time during the study, this may lead to symptoms such as dizziness, headache, stomach upset, or fainting. The high-fat breakfast is a big breakfast containing eg, 2 fried eggs, fried potatoes and bacon. The volunteer must consume the whole breakfast within 20 minutes. It can be difficult to consume the entire breakfast, particularly for light eaters.

Questionnaires:
We will ask the volunteer to complete a questionnaire about sleepiness, a questionnaire about alertness, calmness and contentment, and a questionnaire about potential effects of the study compound.

Coronavirus test
Samples for the coronavirus test will be taken from the back of the volunteers nose and throat using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the volunteers throat may cause the volunteer to gag. When the sample is taken from the back of the volunteers nose, the volunteer may experience a stinging sensation and the volunteers eyes may become watery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Sex: male or female.
2. Age: Part A and B - 18 to 55 years, inclusive, at screening. Part C - 18 to 35 years, inclusive, at screening
3. Body mass index (BMI): 18.0 to 30.0 kg/m2, inclusive, at screening.
4. At screening, females may be of childbearing potential but not pregnant or lactating, or they may be of nonchildbearing potential (either surgically sterilized or physiologically incapable of becoming pregnant, or at least 1 year postmenopausal [amenorrhea duration of 12 consecutive months]); nonpregnancy will be confirmed for all females by a serum pregnancy test conducted at screening, (each) admission, and at follow-up.
5. Female subjects of childbearing potential who have a fertile male sexual partner must agree to use adequate contraception from at least 4 weeks prior to (first) administration of the study drug until 90 days after the follow up visit. Adequate contraception is defined as using hormonal contraceptives or an intrauterine device combined with at least 1 of the following forms of contraception: a diaphragm, a cervical cap, or a condom. Total abstinence from heterosexual intercourse, in accordance with the lifestyle of the subject, is also acceptable.

Further criteria apply

Exclusion criteria

1. Previous participation in the current study.

2. History of relevant drug and/or food allergies.
3. Allergy or hypersensitivity to active ingredient or excipients..
4. Using nicotine-containing products within 60 days prior to (the first) drug administration.
5. History of alcohol abuse or drug addiction (including soft drugs like cannabis products) within 1 year prior to screening.

Further criteria apply

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:	Completed
Start date (anticipated):	09-02-2022
Enrollment:	107
Type:	Actual

Ethics review

Approved WMO Date:	27-12-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-02-2022

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-07-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-08-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-11-2022
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	EUCTR2021-006368-26-NL
CCMO	NL80047.056.21

Study results

Date completed: 10-02-2023

Results posted: 19-09-2023

First publication
04-09-2023