A randomised, double*blind, placebo*controlled, first*time*in*human study to determine the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of MT-4129 in healthy subjects; including the effect of gender and age on the pharmacokinetics of a single dose of MT-4129 in healthy subjects.

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

Summary

ID

NL-OMON43193

Source
ToetsingOnline

Brief title
MT-4129 SAD and MAD study.

Condition

- Other condition

Synonym
heartfailure and renal disorders., hypertension

Health condition

hoge bloeddruk, hartfalen en nierziekten.

Research involving
Human

Sponsors and support

Primary sponsor: Mitsubishi Tanabe Pharma Corporation (MTPC)
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: Diseases associated with aldosterone, MT-4129

Outcome measures

Primary outcome

To investigate the safety and tolerability of ascending single and multiple

oral doses of MT-4129 in healthy subjects.

Secondary outcome

To investigate the pharmacokinetic (PK) profile of MT-4129 after single and

multiple ascending oral doses in healthy subjects

To investigate the pharmacodynamic (PD) parameters (e.g., plasma aldosterone

and serum cortisol concentration) after single and multiple oral doses of

MT-4129 in healthy subjects

To evaluate the effect of gender and age on the PK and PD of MT-4129 after

administration of single oral doses in healthy subjects

Study description

Background summary

MT-4129 is a new investigational compound that may eventually be used for the treatment of diseases associated with aldosterone. MT-4129 inhibits an enzyme (protein) called aldosterone synthase (also called CYP11B2). Aldosterone synthase is involved in the synthesis of aldosterone in the adrenal cortex. Aldosterone plays an important role in the regulation of blood pressure. Inhibition of aldosterone synthase is expected to be used in the treatment for hypertension, heart failure and renal disorders. This is the first time that MT-4129 is being given to humans.

Study objective

The study will be performed in 4 parts, Parts 1 to 4. In Parts 1, 3 and 4, single doses of MT-4129 will be administered whereas in Part 2, multiple doses of MT-4129 will be administered. The purpose of the study is to investigate how safe MT-4129 is and how well MT-4129 is tolerated.
It will also be investigated how quickly and to what extent MT-4129 is absorbed by and eliminated from the body (this is called pharmacokinetics). Further, the effect of the compound on certain proteins in your blood will be investigated (this is called pharmacodynamics). In addition, the effect of gender (Part 3) and age (Part 4) on MT-4129 pharmacokinetics and pharmacodynamics will be investigated. This study will be performed in a maximum of 136 healthy volunteers.

Study design

Part 1
Part 1 will be performed in a maximum of 9 dose groups each consisting of 8 healthy male Caucasian volunteers aged 18 to 55 years. Volunteers will participate in 1 of these 9 dose groups.There will be 1 treatment period for each volunteer. Part 1 will be performed in a maximum of 72 healthy male volunteers.

Part 2
Part 2 will be performed in a maximum of 4 dose groups each consisting of 12 healthy male volunteers. Volunteers will participate in 1 of these 4 dose groups. There will be 1 treatment period for each volunteer. Part 2 will be performed in a maximum of 48 healthy male volunteers.

Part 3 (gender effect)
Part 3 will be performed in 1 dose group consisting of 8 healthy female Caucasian volunteers aged 18 to 55 years. There will be 1 treatment period for

each volunteer.

Part 4 (age effect)
Part 4 will be performed in 1 dose group consisting of 8 healthy male Caucasian volunteers aged 65 years or higher. There will be 1 treatment period for each volunteer.

Intervention

First group day 1; 5 milligrams (mg) MT-4129 or placebo sober 1 capsul once
Second group day 1; 10 mg MT-4129 or placebo sober 1 capsul once
Third group day 1: 20 mg MT-4129 or placebo sober 1 capsul once
Fourth group day 1; 50 mg MT-4129 or placebo sober 1 capsul once
Fifth group day 1: 100 mg MT-4129 or placebo sober 1 capsul once
Sixth group day 1; 200 mg MT-4129 or placebo sober 2 capsules once
Seventh group day 1; 400 mg MT-4129 or placebo sober 4 capsules once
Eighth group day 1; 800 mg MT-4129 or placebo sober 8 capsules once
Nineth group day 1; TBD mg MT-4129 or placebo sober TBD capsules once

Part 2: The volunteers will receive either MT-4129 or placebo once daily for 7 days (from Day 1 to Day 7). This period may be prolonged to a maximum of 14 days. MT-4129 and placebo will be given in the form of oral capsules.

Study burden and risks

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

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

Parts 1 and 4: healthy male/ Part 3: healthy female
Parts 1 and 3: 18 - 55 years, inclusive/Part 4: 65 years of age or older
Parts 1, 3 and 4: Caucasian (person belonging to or originate from one of the original people of Europe, the Middle East, North Africa, or the Indian subcontinent)
Parts 1 and 4: 60 kilograms or higher/Part 3: 50 kilograms or higher
BMI 18.0 - 30.0 kilograms/meter2
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):	29-11-2016
Enrollment:	136
Type:	Actual

Ethics review

Approved WMO Date:	25-10-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-11-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-12-2016
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	EUCTR2016-003500-32-NL
CCMO	NL59584.056.16