A randomised, double-blind, placebo-controlled, study to investigate the safety, tolerability and pharmacokinetics of single ascending doses of MT-2990 in healthy male subjects.

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

Summary

ID

NL-OMON45915

Source
ToetsingOnline

Brief title
MT-2990 SAD study.

Condition

- Other condition

Synonym
inflammation

Health condition

ontstekingsziektes.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: inflamation, MT-2990

Outcome measures

Primary outcome

Primary assessments:

Incidence, nature and severity of adverse events (AEs)

Vital signs (blood pressure, pulse rate and tympanic body temperature)

ECG parameters (including HR and cardiac intervals: PR, QRS, QT and corrected

QT interval using Fridericia*s formula [QTcF])

Clinical laboratory assessments (haematology, biochemistry, coagulation and

urinalysis)

Physical examination.

Secondary outcome

Secondary assessments:

PK assessments

PK concentrations vs. time profile of MT-2990.

The following PK parameters of MT 2990 will be calculated after single dosing:

Cmax

Time to Cmax (tmax)

t*

AUC0-last

AUC0-*

Terminal elimination rate constant (Kel)

Apparent volume of distribution at steady state (Vss)

Apparent volume of distribution during the terminal phase after IV

administration (Vz)

Mean residence time from time zero to infinity (MRT0-*)

Apparent serum clearance (CL)

Percentage of AUC obtained by extrapolation (%AUCex).

Immunogenicity

Proportion of subjects who develop antibodies against MT-2990 in serum.

Study description

Background summary

MT-2990 is a new investigational compound that may eventually be used for the treatment of diseases where interleukin 33 (IL-33) causes inflammation. IL-33 is a cytokine, which is a small protein with which cells communicate in the body. IL-33 causes inflammation in the body and can be involved in diseases such as asthma, allergy, atopic dermatitis, inflammatory bowel disease and also in cardiovascular disease.
Antibodies are produced by our own body for host defense against for example bacteria and viruses. However, antibodies can also be designed and prepared, so that they can be used for the treatment of diseases. MT-2990 is an antibody designed such that it can specifically recognize and bind IL-33 and thereby block inflammation caused by IL-33. Correspondingly, MT-2990 may inhibit inflammation in diseases. This is the first time that MT-2990 is being given to humans.

Study objective

The purpose of the study is to investigate how safe MT-2990 is and how well MT-2990 is tolerated. It will also be investigated how quickly and to what extent MT-2990 is distributed in and eliminated from the body (this is called pharmacokinetics). In addition, it will be investigated to what extent the body produces antibodies against MT-2990. This study will be performed in a maximum of 48 healthy male volunteers. There will be a maximum of 6 dose groups each consisting of 8 healthy male volunteers. The volunteers will participate in 1 of these 6 dose groups. This study is not intended to improve the health or benefit the volunteer in any way, but is necessary for the further development of MT-2990.

Study design

The actual study will consist of 1 period during which the volunteers will stay in the clinical research center for 4 days (3 nights): this will be from the afternoon of Day -1 (the day before administration of the study compound; also called admission) to the morning of Day 3. They are expected at the clinical research center on Day -1 at 14:00 h in the afternoon. They will be required not to have consumed any food or drinks (with the exception of water) during the 4 hours prior to arrival in the clinical research center. They will leave the clinical research center on Day 3.
Subsequently, they will visit the clinical research center for short ambulatory visits on Days 8, 15, 29 and 57. For these short ambulatory visits,they will arrive at the clinical research center between 11:00 h and 14:30 h. They will be required not to have consumed any food or drinks (with the exception of water) during the 4 hours prior to arrival in the clinical research center. The follow-up visit will take place on Day 85.
In consultation with PRA, the short ambulatory visits on Days 15, 29 and 57, and the follow-up visit may be scheduled 1 day earlier or 1 day later.
The participation to the entire study, from the screening visit until the follow-up visit, will be a maximum of 114 days.

Intervention

Group 1, Day 1, 0.1 mg/kg MT-2990 or placebo administered as a 1 hour single dose IV infusion
Group 2, Day 1, 0.3 mg/kg MT-2990 or placebo administered as a 1 hour single dose IV infusion
Group 3, Day 1, 1 mg/kg MT-2990 or placebo administered as a 1 hour single dose IV infusion
Group 4, Day 1, 3 mg/kg MT-2990 or placebo administered as a 1 hour single dose IV infusion
Group 5, Day 1, 10 mg/kg MT-2990 or placebo administered as a 1 hour single dose IV infusion

Study burden and risks

Pain, minor bleedings, bruises and possibly an infection.

Contacts

Public
Mitsubishi Tanabe Pharma Corporation

Nihonbashi-Koamicho, Chuo-ku 17-10
Tokyo 103-8405
JP
Scientific
Mitsubishi Tanabe Pharma Corporation

Nihonbashi-Koamicho, Chuo-ku 17-10
Tokyo 103-8405
JP

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 of age, inclusive
BMI 18 - 30 kilograms/meter2, inclusive
weight 60 - 100 kilograms, 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
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):	08-05-2017
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-05-2017
Application type:	First submission
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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	EUCTR2016-005036-15-NL
CCMO	NL61497.056.17