A study to evaluate the pharmacokinetics, safety and tolerability after inhalation of MMI-0100 in healthy subjects; MMI-0100 is an investigational drug developed for the treatment of fibrotic indications.

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Primary:To determine the safety and tolerability of pulmonary administered MMI-0100 after a single dose, as assessed by adverse events (AE), vital signs, physical exam, clinical laboratory safety assessments, lung function tests and...

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

Summary

ID

NL-OMON40896

Source
ToetsingOnline

Brief title
MMI-0100 SAD study.

Condition

- Other condition

Synonym
Idiopathic pulmonary fibrosis, pulmonary diseases.

Health condition

idiopathische fibrose

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fibrotic indications, MMI-0100

Outcome measures

Primary outcome

PK:

Plasma MMI-0100 drug concentrations. PK parameters, including area under the concentration-time curve (AUC), maximum plasma concentration (Cmax), time to attain maximum plasma concentration (Tmax), and elimination half life (t1/2) will be determined, if possible. Comparisons across dose levels will be made to assess proportionality.

Safety:

AEs, vital signs, 12-lead ECG, clinical laboratory, physical examination, pulmonary function tests. Pulmonary function tests comprise forced (expiratory) vital capacity (FVC), forced expiratory volume over one second (FEV1) and vital capacity (VC). In addition TLC and DLCO will be done.

Secondary outcome

Not applicable.

Study description

Background summary

MMI-0100 is a new investigational compound that may eventually be used for the treatment of idiopathic pulmonary fibrosis and other fibrotic indications. Fibrosis is associated with an increase of fibrous tissue in organs. This inflammatory pulmonary disease is affected by a cascade reaction which synthesize and release of pro-inflammatory cytokines (a cytokine is a small protein involved in the most defense mechanisms associated with infections). MMI-0100 inhibits a part of this cascade reaction and therefore may inhibit the inflammation process in the lungs. This is the first time that this compound is being given to humans.

Study objective

Primary:
To determine the safety and tolerability of pulmonary administered MMI-0100 after a single dose, as assessed by adverse events (AE), vital signs, physical exam, clinical laboratory safety assessments, lung function tests and electrocardiography (ECG) parameters.

Secondary:
To characterize the systemic pharmacokinetics (PK) of MMI-0100 following a single pulmonary administration.

Study design

This study is a phase I, randomized, double-blind, dose escalating, placebo-controlled study in healthy volunteers with MMI-0100 administered by pulmonary delivery. This is a single ascending dose study to investigate the safety, tolerability, and PK of pulmonary administered MMI-0100 in 7 sequential cohorts of up to 8 healthy subjects.

Intervention

The study will consist of 1 period(s) during which the volunteer will receive MMI-0100 once or placebo once. MMI-0100 and placebo will be given in the form of an inhalation.

Study burden and risks

During the study, various studies are carried out that can be experienced as more or less stressful.

Blood sampling, indwelling cannula:
During this study less than 200 milliliters of blood will be drawn. At Day -1 an indwelling cannula will be inserted in your arm once to collect blood on Day 1. On other days blood will be drawn using a needle inserted directly into a vein in your arm.

Inhalation:
The study medication will be administered using the eFlow® device. The eFlow® is a reusable electronic inhalation system designed for the treatment of diseases of the respiratory system and lungs. Each participant will receive a single-use hand set for the delivery of the test article.

Vital signs:
Blood pressure, pulse rate and body temperature will be measured regularly

Heart trace (ECG):
ECGs will be made regularly

Pulmonary function tests:
Pulmonary function tests will be carried out regularly at screening and during the study. For this test you will be asked to exhale as hard as you can and to exhale as much as you can into a special device. In addition total lung capacity and carbon monoxide diffusion capacity will be performed in the University Medical Center Groningen on Days -1, 1 and 15.

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 and 55 years of age, inclusive
BMI 19.0 and 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 to 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):	19-06-2014
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MMI-0100
Generic name:	MMI-0100

Ethics review

Approved WMO Date:	04-06-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-06-2014
Application type:	First submission
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	EUCTR2014-001010-26-NL
CCMO	NL49419.056.14