A PHASE 1, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL IN HEALTHY VOLUNTEERS TO DETERMINE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF ESCALATING MULTIPLE DOSES OF MMI-0100 OR PLACEBO ADMINISTERED BY PULMONARY DELIVERY

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

Summary

ID

NL-OMON43064

Source
ToetsingOnline

Brief title
MMI-0100 MAD study

Condition

- Other condition

Synonym
Idiopathic pulmoary 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: Fribrotic indications, MMI-0100

Outcome measures

Primary outcome

To determine the safety and tolerability of pulmonary administered MMI-0100

with daily doses for 7 days, as assessed by adverse events (AE), vital signs,

physical exam, clinical laboratory safety assessments, pulmonary function tests

and 12-lead electrocardiogram (ECG) parameters

Secondary outcome

To characterize the systemic pharmacokinetics (PK) of MMI-0100 by inhaled

delivery

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 and inflammatory 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. MMI-0100 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 to what extent MMI-0100 is tolerated after multiple administrations.
It will also be investigated how quickly and to what extent MMI-0100 is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, the effect of MMI-0100 on the lung function will be investigated (this is called safety).

Study design

The study will consist of 1 period during which the subject will receive MMI-0100 or placebo once daily for 7 days. MMI-0100 and placebo will be given as in the form of an inhalation.

Intervention

Group 1: multiple pulmonary doses of 5.0 mg MMI-0100 (n=6) or matching placebo (n=2) once daily for 7 days
Group 2: multiple pulmonary doses of 10.0 mg MMI-0100 (n=6) or matching placebo (n=2) once daily for 7 days
Group 3: multiple pulmonary doses of 20.0 mg MMI-0100 (n=6) or matching placebo (n=2) once daily for 7 days
Group 4*: multiple pulmonary doses of 40.0 mg MMI-0100 (n=6) or matching placebo (n=2) once daily for 7 days
* Based on the results obtained from Group 1, 2 and 3, it may be decided to decrease the 40 mg dose level in Group 4.

Study burden and risks

All potential drugs cause adverse effects; the extent to which this occurs differs. MMI-0100 has been given to humans in 2 studies to date. In a single dose study the most frequently observed adverse effect was cough but this may well be associated to the method of administration as cough was reported more often by volunteers receiving placebo then by volunteers receiving active medication. MMI-0100 was well tolerated in man and there were no adverse effects reported more than once.

MMI-0100 was well tolerated when given via inhalation in animals. Most adverse

events were only observed after direct injection in the body cavity. The most frequent adverse effects were: hypotension (low blood pressure) and vascular inflammation.

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
Age: between 18 and 55 years of age, inclusive
BMI: between 19.0 and 30.0 kilograms/meter2
Body weight: between 50.0 and 100.0 kg, 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):	17-03-2016
Enrollment:	32
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	11-02-2016

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-02-2016
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	EUCTR2015-005595-17-NL
CCMO	NL56730.056.16