# A study to assess the safety, tolerability, and pharmacokinetics of FM101 after single and multiple ascending dose administration to healthy subjects.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27747

**Source**
NTR

**Brief title**
TBA

**Health condition**

NASH (non-alcoholic steatohepatitis)

### Sponsors and support

**Primary sponsor:** Future Medicine Ltd.
**Source(s) of monetary or material Support:** Future Medicine Ltd.

### Intervention

### Outcome measures

**Primary outcome**

1. Part 1, FM101-SAD: Safety as measured by Adverse events (TEAEs), clinical laboratory

values, vital signs, ECGs, and physical examinations .
2. Part 3, FM101-MAD: Safety as measured by Adverse events (TEAEs), clinical laboratory values, vital signs, ECGs, and physical examinations
3. Part 1, Plasma PK assessment: Plasma concentrations of FM101, derived PK parameters
4. Part 3, Plasma PK assessment: Plasma concentrations of FM101, derived PK parameters
[Time Frame: from Day 1 to Day 10].

### Secondary outcome

1. Part 2, Plasma PK assessment: Plasma concentrations of FM101, derived PK parameters after single oral dosing [Time Frame: from Day 1 to Day 4].

## Study description

### Background summary

This is a randomized, double-blinded, placebo-controlled, alternating single ascending dose (SAD), sequential multiple ascending dose (MAD) and food effect (FE) study in 50 healthy male and female volunteers.
The study is conducted in the Netherlands.

### Study objective

This is a Phase I study (not a hypothesis-driven).

### Study design

SAD [Day 1 to Day 7]; FE [Day 1 to Day 4]; MAD [Day1 to Day 10]

### Intervention

Drug: FM101 oral solution
Other: Placebo matching FM101 oral solution

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Gender : male or female
2. Age : 18 - 50 years, inclusive, at screening
3. Body mass index (BMI) : 18.0 – 32.0 kg/m2 (inclusive)
4. Weight : ≥ 50 kg
5. Status : healthy subjects
6. At screening, females must be non-pregnant and non-lactating, or of non childbearing potential (either surgically sterilized or physiologically incapable of becoming pregnant, or at least 1 year post menopausal [amenorrhea duration of 12 consecutive months); non-pregnancy will be confirmed for all females by a serum pregnancy test conducted at screening, and a urine pregnancy test at each admission and at follow-up.
7. Female subjects of child-bearing potential, with a fertile male sexual partner, must agree to use adequate contraception from screening 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 or cervical cap, or a condom. Also, total abstinence, in accordance with the lifestyle of the subject, is acceptable.
8. Male subjects, if not surgically sterilized, must agree to use adequate contraception and not donate sperm from first admission to the clinical research center until 90 days after the follow-up visit. Adequate contraception for the male subject (and his female partner) is defined as using hormonal contraceptives or an intrauterine device combined with at least 1 of the following forms of contraception: a diaphragm or cervical cap, or a condom. Also, total abstinence, in accordance with the lifestyle of the subject is acceptable.
9. All prescribed medication must have been stopped at least 14 days prior to (each) admission to the clinical research center. An exception is made for hormonal contraceptives, which may be used throughout the study.
10. All over-the-counter medication, vitamin preparations and other food supplements, or herbal medications (eg, St. John’s Wort) must have been stopped at least 7 days prior to (each) admission to the clinical research center. An exception is made for paracetamol, which is allowed up to admission to the clinical research center.
11. Ability and willingness to abstain from alcohol, methylxanthine-containing beverages or food (coffee, tea, cola, chocolate, energy drinks), grapefruit (juice), and tobacco products from 48 hours prior to (each) admission to the clinical research center.
12. Good physical and mental health on the basis of medical history, physical examination, clinical laboratory, ECG, and vital signs, as judged by the Investigator.

13. Willing and able to sign the ICF.

### Exclusion criteria

1. Employee of CRO or the Sponsor.
2. History of relevant drug and/or food allergies.
3. Using tobacco products within 60 days prior to (the first) drug administration.
4. History of alcohol abuse or drug addiction (including soft drugs like cannabis products).
5. Positive drug and alcohol screen (opiates, methadone, cocaine, amphetamines [including ecstasy], cannabinoids, barbiturates, benzodiazepines, gamma hydroxybutyric acid [GHB], tricyclic antidepressants, and alcohol) at screening and (each) admission to the clinical research center.
6. Average intake of more than 24 units of alcohol per week (1 unit of alcohol equals approximately 250 mL of beer, 100 mL of wine, or 35 mL of spirits).
7. Positive screen for hepatitis B surface antigen (HBsAg), anti hepatitis C virus (HCV) antibodies, or anti human immunodeficiency virus (HIV) 1 and 2 antibodies.
8. Participation in a drug study within 60 days prior to (the first) drug administration in the current study. Participation in more than 3 other drug studies (for male subjects) / more than 2 other drug studies (for female subjects) in the 10 months prior to (the first) drug administration in the current study.
9. Donation or loss of more than 100 mL of blood within 60 days prior to (the first) drug administration. Donation or loss of more than 1.5 liters of blood (for male subjects) / more than 1.0 liters of blood (for female subjects) in the 10 months prior to (the first) drug administration in the current study.
10. Significant and/or acute illness within 5 days prior to (the first) drug administration that may impact safety assessments, in the opinion of the Investigator.
11. Non-willingness to consume the high-fat breakfast (Part B only).
12. Unsuitable veins for infusion or blood sampling.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 29-01-2019 |
| Enrollment: | 50 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** No

# Ethics review

Positive opinion

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|---|---|
| Date: | 11-02-2019 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 48530
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL7515 |
| CCMO | NL68308.056.18 |
| OMON | NL-OMON48530 |

# Study results