# A first-in-human, single-centre, placebo-controlled, randomized, double-blind study in healthy subjects to evaluate safety, tolerability, pharmacokinetics and food effect after oral single and multiple ascending dosing of KAND567

Published: 02-05-2017
Last updated: 12-04-2024

The primary objective is to determine the safety and tolerability of KAND567 following oral single ascending dose (SAD) and multiple ascending doses (MAD) administration in healthy young and elderly subjects.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Demyelinating disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44294

**Source**
ToetsingOnline

**Brief title**
KAN0001 (CS0276)

### Condition

- Demyelinating disorders

**Synonym**
MS, Multiple sclerosis

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Kancera AB
**Source(s) of monetary or material Support:** Kancera AB

## Intervention

**Keyword:** First-in-human, healthy subjects, Pharmacokinetics, Safety

## Outcome measures

### Primary outcome

The safety endpoint parameters are frequency and severity of adverse events,

vital signs, electrocardiography (ECG), safety laboratory tests and urinalysis.

### Secondary outcome

The pharmacokinetic parameters.

# Study description

### Background summary

KAND567 is being developed for the treatment of inflammations and pain in multiple sclerosis (MS).

### Study objective

The primary objective is to determine the safety and tolerability of KAND567 following oral single ascending dose (SAD) and multiple ascending doses (MAD) administration in healthy young and elderly subjects.

### Study design

A first-in-human, single-centre, placebo-controlled, randomized, double-blind study.

### Intervention

The study will start with a screening. At the screening a physical examination

will take place and a few other standard medical assessments will be performed (ECG,vital signs). Furthermore a blood and urine sample will be taken for laboratory tests and an alcohol breathtest and drug screen will be done.

During the stay in the clinic the subject will receive the study medication and on several time pointsblood will be taken and urine will be collected. The subjects will be asked for possible side effects on regular basis. Furthermore several safety assessments will be done frequently.

Finally, a follow-up visit will take place.

**Study burden and risks**

The study drug KAND567 has not been administered to humans before. KAND567 has been administered to animals, as required by regulatory (health) authorities. The dose has been selected based on the results of animal testing. The health risks are limited at these dose levels, but you can possibly experience side effects. In animals a number of side effects have been observed after administration of KAND567. These side effects were changes in kidney function due to reversible renal damage and changes in liver function. In addition, decreased heart rate and decreased blood pressure occurred in animals.
The blood collection procedure is not dangerous, but may cause discomfort or bruising. Occasionally, fainting, bleeding or an infection at the blood sampling site can occur.
There are indications that in humans the function of the liver may temporarily be disturbed after administration of KAND567 and that skin rashes may occur.

# Contacts

**Public**
Kancera AB

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**Scientific**
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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 and female

## Exclusion criteria

Clinical significant abnormalities at medical research

# 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): | 22-05-2017 |

| | |
|---|---|
| Enrollment: | 98 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 02-05-2017 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 08-05-2017 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 18-07-2017 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 02-10-2017 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 05-10-2017 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 18-10-2017 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 19-10-2017 |

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| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 06-11-2017 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 07-11-2017 |
| 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 | EUCTR2017-001457-13-NL |
| CCMO | NL61640.056.17 |