Clinical trial of a new compound that is being developed for the treatment of neurological diseases, such as dementia

Clinical trial code-21937X

Type of study

Soon a clinical trial will start at ICON with a new compound that is being developed for the treatment of neurological diseases, such as dementia.

The trial will investigate how quickly and to what extent the study compound is distributed and eliminated from the body. In addition, it will also be investigated how safe the study compound is and how well it is tolerated when it is used by healthy participants. The effects of the study drugs are compared to the effects of a placebo (drug with no active ingredient).

The study compound has not been administered to humans before, but it has been extensively tested in the laboratory and on animals. This trial is not intended to improve your health but is necessary for the further development of this compound. The trial will only take place after it has been approved by the Independent Ethics Committee (METC).

Setup and duration of the trial

This trial will be executed in healthy male and female participants. This trial consists of two parts: part A and part B. Part B is divided in cohort 1 to 3 and cohort 4. You can participate only once in this trial.

To check if you are eligible to participate a medical screening will take place before the start of the trial. Depending on availability, this can be performed in Groningen or Utrecht. This screening will take place within 4 weeks before the start of the clinical trial.

Part A of the trial consists of 1 period during which you will stay in the research facility in Groningen for 6 days (5 nights), followed by 5 short visits to the research facility, and a final follow-up visit 4 weeks thereafter. The total study duration from dosing until the final follow-up visit will be approximately 85 days.

Cohorts 1 to 3 of part B of the trial consist of three 2-week periods. The first period has a stay of 4 days (3 nights) and the next two periods have a stay of 3 days (2 nights) in the research facility in Groningen. Each stay is followed by two short visits to the research facility. After these three periods, another three short visits to the research facility will follow, and a final follow-up visit 4 weeks thereafter. The total study duration from dosing until the final follow-up visit will be approximately 113 days.

Cohort 4 of part B of the trial consists of three 4-week periods. The first period has a stay of 4 days (3 nights) and the next two periods have a stay of 3 days (2 nights) in the research facility in Groningen. Each stay is followed by three short visits to the research facility. After these three periods, another two short visits to the research facility will follow, and a final follow-up visit 4 weeks thereafter. The total study duration from dosing until the final follow-up visit will be approximately 141 days.

You will be given the study compound or placebo as an intravenous infusion (solution of the compound that will be administered directly in a blood vessel). In part A, you will receive the study compound or placebo once. In cohort 1 to 3 of part B, you will receive the study compound or placebo three times, once every two weeks. In cohort 4 of part B, you will also receive the study compound or placebo three times, but then once every four weeks. Whether you will receive the study compound or placebo will be determined by chance.

During the trial, blood will regularly be drawn and urine will be collected. Prior to the screening visit, (each) entry into the research center and the final follow-up visit, you will have to stay fasted for 4 hours. You can only drink water prior to your visit. This means that we will ask you to fast prior to the screening in the screening center. You

will not yet have signed the form for approval of participation in the study, but that will be done before the screening starts. After the screening it will be announced whether you can participate.

Use of medication, herbal medications, vitamin preparations and other food supplements, and consumption of alcohol, coffee, tea, cola, power drinks, chocolate (including chocolate milk), grapefruit, tangelo, pomelo, Seville oranges (including their juices or marmalade), poppy seeds, tobacco and other nicotine containing products are not allowed during the trial. Also, before the start of the trial and when you are not staying in the research facility, there will be restrictions for some of these products. Use of decaffeinated coffee and (herbal) teas without caffeine (also called theine) is allowed.

Risks and medical supervision

All potential medicines can cause side effects. As the study compound will be administered to humans for the first time in this study, side effects of study compound in humans are not known yet. The study compound has been studied extensively in the laboratory and in animals.

You should take into account that (serious) side effects may occur that are still unknown. In addition to unknown side effects, there is a (small) chance that an allergic reaction will occur. This can be caused by the study compound or other ingredients that are used to prepare the formulation. During the study, you will be under strict medical supervision. The doctors and investigators of ICON are always well-informed about the compound being studied. With this knowledge they can estimate the effects and side effects reasonably well.

Conditions for participation

- You are a healthy male or female.
- You are at least 18 and no more than 55 years old .
- You weigh between 50 and 110 kg and your Body Mass Index (BMI) is higher or equal to 18.0 and lower or equal to 32.0 kg/m^2. The BMI shows the relationship between body weight in kilograms and height in meters.
- You did not smoke in the 3 months prior to screening.

Note:

- You cannot participate in the trial if you have participated in another clinical trial in the 30 days prior to the first study drug administration in this clinical trial (counting from the follow-up visit of the previous trial).
- To determine if you are suitable to participate in this trial, you will undergo a medical screening. Depending on availability, this can be performed in Groningen or in Utrecht.
- As a **female** you can only participate if you are not pregnant, not breast feeding, and meet one of the following conditions:
    - Younger than 35 years old: you use hormonal or non-hormonal contraception (for example the contraceptive pill or intra-uterine device) in combination with a condom;
    - Older than or equal to 35 years old: you have a copper intrauterine device and use a condom in combination with it; no hormonal contraception is allowed;
    - You have passed the menopause (no periods for at least 12 months);
    - You have been sterilized or your male partner has been sterilized;
    - You are only sexually active with a partner of the same sex;
    - You are not sexually active according to your lifestyle.
- As a **male** you can only participate if you meet one of the following conditions:
    - You use a condom in combination with an additional contraception method used by your female partner;
    - You have been sterilized or your female partner is sterilized or has passed the menopause (no periods for at least 12 months);
    - You are not sexually active according to your lifestyle;
    - You are only sexually active with a partner of the same sex

Compensation

You will receive a gross compensation of € 2904 for full participation in one of the groups of part A. For full participation in cohort 1 to 3 of part B, you will receive a gross compensation of € 4510. For full participation in cohort 4 of part B, you will receive a gross compensation of € 5005.
Travel expenses will be reimbursed based on the distance traveled (€ 0.21 net per kilometer) with a minimum of € 13 and a maximum of € 176.40 (840 kilometers) per round trip, regardless of the mode of transportation.

Do you want to know more?

Please call ICON on business days between 8:30 AM and 8:00 PM or on Saturday between 10:00 AM and 4:00 PM on the following numbers:

Netherlands:	0800-0292044
Belgium:	0800-89036
Germany:	0800-0713579/ 0031-50-8505798

Or send an e-mail to info@geneesmiddelenonderzoek.nl. When calling or sending an e-mail, please quote the indicated trial code (clinical trial code-21937X). Alternatively, you can visit www.iconclinicaltrials.com.