Clinical trial of a new compound that is being developed for the treatment of inflammatory diseases

Clinical trial code-21928X

Type of study

Soon a clinical trial will start at ICON with a new compound that is being developed for the treatment of inflammatory diseases.

In this trial, we investigate how safe the new compound is and how well it is tolerated when it is administered to healthy participants. Furthermore, we investigate how quickly and to what extent the new compound is absorbed, transported, and eliminated from the body (this is called pharmacokinetics). We compare the effects of the compound with the effects of a placebo. A placebo is a compound without any active ingredient.

The compound has not been used by humans before. 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) from the Foundation for the Assessment of Ethics for Biomedical Research in Assen.

Setup and duration of the trial

This trial will be executed in maximum of 112 healthy male and female participants. The trial consists of 2 parts: part A and part B. You can only participate in one part of 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 approximately within 4 weeks before the start of the clinical trial.

Part A: The trial consists of 1 period during which you will stay in the research facility in Groningen (location van Swietenlaan 6) for 6 days (5 nights), followed by 5 short visits including the follow-up visit.

Part B: The trial consists of 4 periods during each of which you will stay in the research facility in Groningen (location van Swietenlaan 6). The periods are set-up as follows: The first period is 10 days (9 nights), followed by 2 periods of 3 days (2 nights), concluded by the last period of 6 days (5 nights). After the last period there are 7 more short visits including the follow-up visit.

In part A you will receive the new compound once. You will be given the compound or placebo as an intravenous infusion (solution of the compound that will be administered directly in a blood vessel) or as an injection under the skin (subcutaneous) in part A. In part B you will receive the new compound 5 times. You will be given the compound or placebo as an injection under the skin (subcutaneous) in part B.

Prior to screening, (each) admission, the short visits and the follow-up, you have to stay fasted for 4 hours. You can only drink water prior to your visit until 1 hour before due to covid testing. This means that we will ask you to fast prior to any participation in the trial. You have not yet signed the form for participation in the trial. After the screening it will be announced whether you can participate.

There are no specific meals in this study. Consumption of medication, alcohol, poppy seeds, coffee and tea, cola, power drinks and chocolate (including chocolate milk), grapefruit (including juice) are not allowed during the trial. Excessive exposure to sunlight must be avoided 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 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 compound will be administered to humans for the first time in this trial, side effects in humans are not known yet. The 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 between 18 and 60 years old.
- Your Body Mass Index (BMI) is between 18.0 and 32.0 kg/m2.
- Both non-smokers and light smokers or occasional smokers (who smoke no more than 5 cigarettes per day) are allowed to participate in this clinical trial. From one week prior to admission and during your stay in our research facility you are not allowed to smoke.

- **Note:**

  - You cannot participate in the trial if you have participated in another clinical trial in the 3 months prior to the first compound administration in this clinical trial (counting from the follow-up visit).
  - For this trial, you cannot (have) receive(d) a COVID-19 vaccine within 14 days prior to the start until 14 days after the last compound administration.
  - 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:
    - You are using hormonal contraception (for example the contraceptive pill or intra-uterine device containing hormones) from at least 4 weeks prior to admission;
    - You are using a copper intra-uterine device from at least 4 weeks prior to admission;
    - 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 not sexually active according to your lifestyle;
    - You are only sexually active with a partner of the same sex.
  - As a **male** you can only participate if you meet one of the following conditions:
    - You are using a condom in combination with an additional contraception method used by your fertile female partner from at least 4 weeks prior to your admission;
    - 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 € 2390 for participation in one of the groups of part A. For participation in one of the groups of part B of the trial, you will receive a gross compensation of € 5980. Travel expenses will be reimbursed based on the distance traveled (€ 0.19 net per kilometer) with a minimum of € 12 and a maximum of € 160 (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-21928X). Alternatively, you can visit www.iconclinicaltrials.com.