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

Clinical trial code-22307X

Type of study

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

This trial investigates the blood levels of the study compound. It will be investigated how quickly and to what extent different compositions of the study compound are absorbed, transported, and eliminated from the body. It will also be investigated how safe the study compound is and how well it is tolerated.

The study compound will be injected under the skin (this is called subcutaneous administration) of the abdomen. We will compare two different administration methods: a syringe and a pen-injector. A pen-injector is a device that is developed to make injections more easy and convenient. They are for example used by diabetes patients to inject insulin.

The study compound has already been administered to patients with chronic kidney disease or rheumatoid arthritis. It has only been given to patients in a research setting. The current study will be the first study where the study compound will be given to healthy participants.
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. 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.

The trial consists of a total of 14 short visits, so there is no overnight stay in the research facility in Groningen. After that, the follow-up visit will take place.

You will receive the compound once. You will be given the compound as an injection under the skin (subcutaneous) of the abdomen. There are 3 different study treatments in this study. You will receive one of them. Which study treatment you will receive will be determined by drawing lots. You have an equal chance to receive each study treatment.

During the trial, blood will regularly be drawn and urine will be collected. You have to sign the form for approval of participation in the study before the screening starts. After the screening it will be announced whether you can participate.

Consumption of medication, alcohol, tobacco and other nicotine containing products is not allowed the day before the dosing visit, and is limited to 5 cigarettes or the equivalent per day. Also, before the start of the trial and when you are not staying in the research facility, there will be restrictions for these products.

Risks and medical supervision

All potential medicines can cause side effects. The compound has already been studied in patients with chronic kidney disease or rheumatoid arthritis. A possible side effect may be an infection, which may occur when bacteria, virus or other microorganisms enters a person’s body and causes harm. Signs of infection can be different, but often include fever, feeling very tired, and sweats or chills. Infections can also have no signs or signs that are so

mild that you may not notice, but these infections will be shown by a blood test. We do not know how often these side effects may happen.

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 64 years old.
- Your Body Mass Index (BMI) is higher than or equal to 18.5 and lower than or equal to 29.9 kg/m2. The BMI shows the relationship between body weight in kilograms and height in meters.
- Both non-smokers and light or occasional smokers are allowed to participate in this clinical trial. However, during your visits 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 30 days prior to the screening of 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:
    - You use contraception (for example the contraceptive pill or intra-uterine device) in combination with a condom;
    - You have passed the menopause (no periods for at least 12 months) and you are more than 45 years old;
    - You have been sterilized or your male partner has been sterilized;
    - You are only sexually active with a female;
    - You are not sexually active according to your lifestyle.
- For **males**, there are no requirements regarding contraception

Compensation

You will receive a gross compensation of € 4034 for full participation. Travel expenses will be reimbursed based on the distance traveled (€ 0.21 net per kilometer) with a minimum of € 13 and a maximum of € 177 (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-22307X). Alternatively, you can visit www.iconclinicaltrials.com.