Clinical trial of a new compound that is being developed for the treatment of cardiac arrythmias

Clinical trial codeAP31969-M101/2153AX

Type of study

Soon a clinical trial will start at ICON with a compound that may potentially be used for the treatment of atrial fibrillation. Atrial fibrillation is a common heart rhythm disorder with a rapid, non-regular heartbeat.

In this trial, we investigate how safe the new compound is and how well it is tolerated when it is administered to healthy participants.

We will also investigate how quickly and to what extent the study compound is absorbed, transported, and eliminated from the body. In addition, we look at the effect of food on the absorption of the study compound.

We will compare the effects of the new compound with the effects of a placebo. A placebo is a compound without any active ingredient.

The compound has not been administered to humans before. It has been extensively tested in the laboratory and on animals. The study compound will be tested at various dose levels.

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. The trial consists of 2 parts. 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.

You will be given the study compound as oral tablets with 240 milliliters (mL) of (tap) water.

Part A: The trial consists of 1 period during which you will stay in the research facility in Groningen (location van Swietenlaan 6) for 5 days (4 nights). The follow-up visit will take place 3 – 5 days after your departure from the research facility. The study compound will be administered once.

Part A (food effect group): The trial consists of 2 periods during each of which you will stay in the research facility in Groningen (location van Swietenlaan 6) for 5 days (4 nights). The follow-up visit will take place 3 – 5 days after your departure from the research facility after the last period. The subjects in this group will receive the study compound once without breakfast (Period 1) and once with a breakfast (Period 2). You will receive a high-fat breakfast with a standard composition, which must be started exactly on time and must be finished within 20 minutes. The high-fat breakfast is a large breakfast, including 2 fried eggs, fried potatoes and bacon or cheese. It can be difficult to consume the entire breakfast, for light eaters.

Part B: The trial consists of 1 period during which you will stay in the research facility in Groningen (location van Swietenlaan 6) for 13 days (12 nights). The follow-up visit will take place 4 – 6 days after your departure from the research facility. The study compound will be administered once or twice a day for 10 days.

During the trial, blood will regularly be drawn and urine will be collected. Prior to screening and (each) admission, you have to stay fasted for 4 hours. Prior to the follow-up, you have to stay fasted for 10 hours. You can only drink water prior to your visit. 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.

Consumption of medication, alcohol, coffee and tea, cola, power drinks and chocolate (including chocolate milk), grapefruit (including juice) and tobacco / 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 could 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 study compound will be administered to humans for the first time in this study, side effects of the compound in humans are not known yet. The study compound has been studied extensively in the laboratory and in animals. Based on the way this study compound works and studies in animals, the following side effects may be seen:
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Blood pressure
Studies in animals have shown that het study compound may cause an increase in blood pressure. However, studies looking at human genes and human studies with another drug that works in a similar way have not shown a risk of increased blood pressure.

Brain effects
For the study compound, signs of tremors and unsteadiness that came and went were seen in dogs at high doses, but not in rats. In human studies with another drug that works in a similar way, no tremors or other brain effects were seen.

Disturbances of the heart rhythm
Many drugs that block heart-related ion channels can increase the risk of certain heart rhythm problems. Studies in animals and cells indicate that the study compound has a low risk of causing this. In human studies with another drug that works in a similar way, no heart rhythm problems were seen.

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 at most 55 years old.
- Your weight is at least 50 kg and your Body Mass Index (BMI) is at least 18.0 and at most 30.0 kg/m2.

- Both non-smokers and light smokers or occasional smokers are allowed to participate in this clinical trial (at most 5 cigarettes per day). 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 30 days prior to this clinical trial (counting from the follow-up visit).
- 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, from 4 weeks prior to the first compound administration in this trial:
  - You are using hormonal contraception (for example the contraceptive pill or intra-uterine device containing hormones) in combination with a condom;
  - You are using a copper intra-uterine device in combination with a condom;
  - 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 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 € 1429 for participation in one of the groups of part A. For participation in the part A food effect group, you will receive a gross compensation of € 2514. For participation in one of the groups of part B of the trial, you will receive a gross compensation of € 3165. 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-2153AX). Alternatively, you can visit www.iconclinicaltrials.com.