Clinical trial of a new compound that is being developed for the treatment of bone density conditions such as osteoporosis

Clinical trial code- XTABHQ02-0D1UOX

Type of study

Soon a clinical trial will start at ICON with a new compound that can potentially be used for the treatment of osteoporosis and other bone loss associated conditions. The study compound has not yet been proven to be safe or effective. Osteoporosis is a disease that weakens your bones. It makes your bones thinner and less dense than they should be. People with osteoporosis are much more likely to experience broken bones.

The study compound is a protein that inhibits the activation of osteoclasts (bone cells that break down bone tissue) which in turn leads to less bone mass loss and could thereby potentially help in the treatment of osteoporosis and other bone loss associated conditions.

The study compound is being compared to Prolia®. Prolia® is a drug that is already approved for use in Europe and the US for the treatment of osteoporosis. Both the study compound and Prolia® contain the same active ingredient, called denosumab.

The purpose of this trial is to compare how quickly and to what extent the study compound and Prolia® are absorbed, broken down, and eliminated from the body.

In addition, the trial will assess the safety and tolerability of the study compound and Prolia®, and how the body responds to each product. We will also look at the effect of the study compound and Prolia® on certain blood values.

The study compound has not been administered to humans or animals before. It has been tested in the laboratory and shown to have the same structure as Prolia® but its safety and effectiveness have not been studied in humans.

This trial is not intended to improve your health but is necessary for the further development of the study compound. The trial will only take place after it has been approved by the Independent Ethics Committee (METC) or the Central Committee on Research Involving Human Subjects (CCMO).

Setup and duration of the trial

This trial will utilize only healthy male 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 6 weeks before the start of the clinical trial.

The trial consists of 1 period during which you will stay in the research facility in Groningen (location van Swietenlaan 6) for 3 days (2 nights), followed by a total of 16 additional visits. The follow-up visit will take place during the last visit approximately 37 weeks after starting the study.

If you participate, you will receive a single 60mg injection of either the study compound or EU-approved Prolia® or US-licensed Prolia®. This will be done on the day after admission in the research center. You will be given either one dose of the compound or one dose of a Prolia product as an injection under the skin (subcutaneous). Whether

you will receive the study compound or EU-approved Prolia® or US-licensed Prolia® will be determined by drawing lots (as if by flip of a coin)

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

On the days you will receive the study compound you will receive standardized meals (a standard composition). This is less standardized on the other days.

Consumption of medication , is not allowed during the entire duration of the trial. Also, before the start of the trial and when you are not staying in the research facility, there will be restrictions for products such as alcohol, coffee and poppy seeds. 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 study compound, EU-Prolia®, and US-Prolia® all have the same active ingredient: Denosumab. The risks associated with the study compound are expected to be similar to those of Prolia®.

The most common side effects with Prolia® (seen in more than 1 patient in 10) are pain in the arms or legs, and bone, joint and muscle pain. Uncommon or rare cases of cellulitis (inflammation of deep skin tissue), hypocalcaemia (low blood calcium), hypersensitivity (allergy), osteonecrosis of the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth or loosening of teeth) and unusual fractures of the thigh bone have been seen in patients taking Prolia®.

Injections are done under the skin. You can get side effects at the injection site such as redness, itchiness, lump of fatty tissue under the skin, and/or hematoma. We will therefore check the injection sites carefully and frequently.

You should take into account that (serious) side effects may occur by participating in this trial 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 trial, you will be under 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.
- You are at least 25 and at most 55 years old.
- Your weight is at least 50 kg and at most 110 kg and your Body Mass Index (BMI) is higher than or equal to 18.0 and lower than or equal to 32.9 kg/m2.
- Both non-smokers and smokers (maximum of 10 cigarettes per day, 2 cigars or 2 pipes per day) are allowed to participate in this clinical trial. You are not allowed to smoke, during the visits in our research facility.

Note:

- You cannot participate in the trial if you have participated in another clinical trial in the 2 months prior to the first compound administration in this clinical trial (counting from the last compound administration in the previous trial).
- To determine if you are suitable to participate in this trial, you will undergo a medical screening that will include a physical as well as laboratory and medical tests to determine eligibility. Depending on availability, this can be performed in Groningen or in Utrecht.

- You can only participate if you meet one of the following conditions both during the study and for 90 days after last administration of the study treatment:
  - 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 € 6373 for participation in this study. 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-XTABHQ02-0D1UOX). Alternatively, you can visit www.iconclinicaltrials.com.