Clinical trial of a new compound that is being developed for the treatment of lung diseases such as lung fibrosis

Clinical trial code-22501X

Type of study

Soon a clinical trial will start at ICON with a new compound that may potentially be used for the treatment of chronic lung diseases, like idiopathic pulmonary fibrosis. This disease is characterized by scarring of the lungs which make it hard for the lungs to get enough oxygen. Symptoms related to this disease are shortness of breath, cough and fatigue and these symptoms may worsen over time. The study compound is found to inhibit the TRPA1 protein which is present in many human cells. TRPA1 is found to cause scarring of the lungs when someone is exposed to triggers that make them cough. By inhibiting this protein it is expected that scarring of the lungs is reduced. Treatment with the study compound is also expected to reduce micro injury of the lungs caused by coughing a lot. Overall taking the study compound may improve the quality of life and reduce death rates in people with chronic lung diseases.

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

Furthermore, we investigate how quickly and to what extent the compound is taken up by the body.

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 been used by humans before. It has also 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 and the Central Committee on Research Involving Human Subjects (CCMO).

Setup and duration of the trial

This trial will be executed in 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 4 weeks before the start of the clinical trial.

The clinical trial consists of 1 period during which you will stay in the research facility in Groningen (location van Swietenlaan 6) for 18 days (17 nights). After the period of stay, you will return for the follow-up. This will take place between 2 and 9 days after your discharge from the research facility.

You will receive the compound once a day on day 1 and day 15 and twice a day from day 3 through day 14. On day 2 no compound or placebo will be given. You will be given the compound or placebo as tablets taken in with a glass of water. During the first 4 hours after morning administration of the study compound you will not be allowed to lie down (except when instructed to do so by one of the investigators), as this may influence the uptake of the study compound. On Day 10 you will receive a high fat breakfast, which must be started exactly on time and must be

finished within 20 minutes. The entire breakfast must be consumed. 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.

During the trial, blood will regularly be drawn and urine will be collected. Prior to screening, admission, and the follow-up, you 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 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 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.

The study compound has been given to humans before in an ongoing trial with 48 healthy male subjects receiving placebo (substance without activity; 12 subjects) or the study compound with doses ranging from 0.5 mg to 40mg as single dose (36 subjects). Based on the data from the completed groups the study compound was safe and well tolerated. The most reported side effects after intake of the study compound or placebo are: fatigue, headache, somnolence (drowsiness) and dizziness.

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.
- You are between 18 and 55 years old.
- Your Body Mass Index (BMI) is between 18.5 and 31.9 kg/m2.
- Both non-smokers and smokers are allowed to participate in this clinical trial. During your stay in our research facility it is not allowed to smoke.

- **Note:**
  - You cannot participate in the trial if you have participated in another clinical trial in the 60 days prior to the first compound administration in this clinical trial (counting from 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.

  - You can only participate if you meet one of the following conditions:
    - You are using a condom with 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 € 4092 for participation in one of the groups of this trial. 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-22501X). Alternatively, you can visit www.iconclinicaltrials.com.