INFORMATION LEAFLET FOR PARTICIPATION IN A RESEARCH STUDY

**Type of study**

Soon a research study will start with a compound used for the treatment of inflammatory bowel disease. The purpose of this study is to investigate the safety and tolerability, the absorption and excretion of the study medication.

This study will be performed in 114 healthy male and female volunteers. The study will only take place after it has been approved by the Independent Ethics Committee and the Health Authorities.

**Setup and duration of the study**

Before the start of the study you will visit the medical screening center in Groningen or Utrecht. During this visit you will be medically screened.

The study consists of 2 parts: Part 1 consist of 1 period during which you will stay in our research facility in Groningen for 6 days (5 nights). Group 3 of part 1 consists of 3 periods during which you will stay in our research facility in Groningen for 6 days (5 nights) each. For every group of part 1 there will be a follow-up visit 3 days after your (last) discharge from the research facility. Finally, there will be a telephone follow-up 7 days later.

Part 2 consist of 1 period during which you will stay in our research facility in Groningen for 19 days (18 nights), followed by 1 short visit 4 days after discharge. Finally there will be a follow-up visit 3 weeks after this short visit.

The compound will be administered as a suspension or an oral tablet.

You can find the exact dates of each group on our website. If the dates do change you will be notified as soon as possible.

**Risks and medical supervision**

The study compound may cause side effects. As the compound will be investigated for the first time in humans, no side effects have been reported to date. However, the compound has been studied extensively in the laboratory and in animals. The compound was generally well tolerated and did not result in changes in measurements of blood pressure, heart rate, heart tracings, behavior and respiratory function. The following side effects are most frequently observed in animal studies with very high doses, higher than the doses given in this study, over a long period: vomiting, reddened skin, excessive salivation, body weight loss and nausea.

The study compound may also have side effects that are still unknown. If during the study more information becomes available regarding adverse events that may be related to the study compound, the responsible doctor will inform you about this.

**Conditions for participation**

You are a healthy male or female between 18 and 55 years old. Your Body Mass Index (BMI) is between 18.0 and 32.0 kg/m² (the BMI reflects the relationship between your body weight in kilograms and your height in square meters). You can only take part in the study if you do not smoke or use other nicotine containing products.

Female subjects of childbearing potential who have a fertile male sexual partner must agree to use highly effective contraception from the start of the study up to 90 days after the final drug administration. Highly effective contraception is defined as:

- Copper intrauterine device.

The above requirements on contraception do not apply if:

- You have been surgically sterilized or are postmenopausal (12 months without amenorrhea).
- Your male partner has had a vasectomy and has a confirmed post-vasectomy semen analysis.
- You practice sexual abstinence during the period mentioned above which is in line with your lifestyle.

Male subjects with a female partner of childbearing potential should use a condom and refrain from donating sperm during the study and for 90 days after administration.

The study will be executed under standardized conditions. Use of your own medication, alcohol, regular coffee and tea, cola, power drinks, chocolate (including chocolate milk) and tobacco products during the study is not allowed. Use of decaffeinated coffee and (herbal) teas without caffeine (also called theine) is allowed. Before you are allowed to take part in the study, you will be medically screened; this screening will take place within four weeks before the start of the study.
Compensation

You will receive a gross compensation of €1031 for full participation in Part 1 or €2859 for full participation in group 3 of Part 1. For full participation in Part 2 you will receive a gross compensation of €3179. Traveling expenses will be reimbursed based on the distance traveled (€0.19 net per kilometer) with a minimum of €12 and with a maximum of €160 (840 kilometers) per return, irrespective of the method of transportation.

Do you have questions or are you interested and do you want to participate?

Please call PRA Health Sciences on Monday through Thursday between 08:30 AM and 08:00 PM or on Friday between 08:30 AM and 05:00 PM on the following numbers:
Netherlands: 0800-0292044
Belgium: 0800-89036
Germany: 0800-0713579
or send an e-mail to info@praclinicaltrials.com. When calling or sending an e-mail, please refer to the indicated study code (PRA-19422X). Alternatively, you can visit www.praclinicaltrials.com.