INFORMATION LEAFLET FOR PARTICIPATION IN A RESEARCH STUDY

Type of study
Soon a research study will start at PRA with a new drug that may eventually be used for the treatment of fungal infections. The purpose of the study is to investigate how safe the study medication is and how well it is tolerated. It will also be investigated how quickly and to what extent the study compound is absorbed and eliminated from the body. The effects of the study compound will be compared to the effects of a placebo. A placebo is a medicine without any active ingredient. The study compound has been administered to humans before. This study is not intended to improve your health, but is necessary for the further development of this study medication. The study will only take place after it has been approved by the Independent Ethics Committee.

Setup and duration of the study
For all groups the study consists of 1 period where you will stay for 10 days (9 nights) in our research center in Groningen (location Martini), followed by 2 short visits to our research center.
Group 1 and group 3 till 6 will receive the study compound on day 1 twice via an intravenous infusion, once after breakfast and once after dinner. From day 2 up to day 7 you will receive 1 intravenous infusion each day after breakfast. Besides this group 3 and higher will receive the registered medication Ondansetron during breakfast, this will potentially reduce the risk of nausea and vomiting after dosing with the study medication.
Group 2 will receive the study compound on day 1 and day 2 twice via an intravenous infusion, once after breakfast and once after dinner. From day 3 up to day 7 you will receive 1 intravenous infusion each day after breakfast.
You will receive the study medication administered as a 3 hour infusion. 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. Upon admission to the clinic you must have fasted for at least 4 hours. Before the start of the study you will visit the medical screening centre. Blood samples will be taken regularly during the study.

Risks and medical supervision
All drugs have the potential to cause adverse events. The study compound has been administered to healthy volunteers in two previous medical-scientific studies. The study compound were administered by an intravenous infusion, orally as a tablet and orally as a liquid. Thus far the study compound has been well tolerated. Across both studies, the most frequently reported side effects were nausea, headache, vomiting, fatigue and dizziness. You should be aware that the aforementioned adverse effects and possibly other, still unknown, adverse effects may occur during the study.
For Ondansetron, the following side effects are known: headache (very common; reported by more than 1 out of 10 people), sensation of warmth or flushing, and constipation (common; by less than 1 out of 10 people), hiccups, hypotension, irregular heart rhythm, chest pain, and uncontrolled bodily movements or shaking (uncommon; by less than 1 out of 100 people).

You will be under strict medical supervision during the study. Before the study and at the end of the study you will undergo an extensive medical screening.

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 30.0 kg/m² (the BMI reflects the relation between your body weight in kilograms and your height in meters). You can only take part in the study if you do not smoke. As a female volunteer you are only allowed to participate in this study if you use a medically acceptable method of contraception (for example hormonal contraceptives or a intrauterine device) or if you are postmenopausal for at least one year or if you are surgically sterilized. Women who are pregnant or breastfeeding are not eligible for participation.

The study will be executed under standardized conditions. Use of your own medication, alcohol, regular coffee and tea, cola, power drinks, chocolate (including products made of chocolate), grapefruit (juice) and tobacco products during the study is not allowed. Also before the study and during each period there will be restrictions for these products. 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. The screening will take place within four weeks before the start of the study.
Compensation

You will receive a gross compensation of € 1327,- for full participation in group 1. You will receive a gross compensation of € 1392,- for full participation in all other groups mentioned above. Traveling expenses will be reimbursed on the basis of kilometers traveled (€ 0.19 net per kilometer) with a minimum of € 12,- per return, and with a maximum of € 160,- (840 kilometers) per return, irrespective of the method of transport.

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 and 20:00 or on Friday between 08:30 and 17:00 on +31 (0)50 8505 798 or send an e-mail to info@geneesmiddelenonderzoek.nl. When calling or sending an e-mail, please refer to the indicated study code (PRA-180541). Alternatively, you can visit www.praclinicaltrials.com.