

STUDY NUMBER: 2600007 PART 2

Dear pioneer,

A study to **treat rheumatoid arthritis** will soon start at our research centre in Edegem.

Are you interested in participating and giving science a boost?

Hereby we would like to give you an overview of the study: duration of **± 20 weeks**.

In this cohort, the study medication will be administered intravenously (through a vein).

INCLUSION CRITERIA

- **You have been diagnosed with rheumatoid arthritis.**
 - **You have been taking a stable dose of medication for your rheumatoid arthritis (Methotrexate, leflunomide, sulfasalazine or hydroxychloroquine) for at least 12 weeks prior to screening.**
- Healthy men/women **between** 18 and 75 years old.
 - BMI: between 18 and 35 kg/m² (inclusive at screening)
 - Weight at least 50 kg (inclusive at screening)
 - Non-smoker or smoking maximum 10 cigarettes (including e-cigarettes and cigars, ...) per day. (*smoking is not permitted during your stay*)
 - Not using any medication, vitamins, or homeopathic substances (*except for medication for the treatment of rheumatoid arthritis*).
 - Contraception:
 - Fertile women:
 - Double contraception method: use of a condom, diaphragm or cervical cap + a spermicide in combination with the pill, contraceptive injection, (copper) IUD, patch, etc. for at least 180 days after administration of the study medication.
 - Abstinence
 - Vasectomy partner
 - Infertile women:
 - postmenopausal (= no menstruation for at least 12 months)
 - OR removal of uterus
 - OR removal of both ovaries
 - OR removal of both fallopian tubes
 - Men:
 - If you have a fertile partner, you must use a condom in combination with an effective method of contraception (birth control pills, contraceptive injection, (copper)IUD, patch, etc....) for at least 180 days after administration of the study medication.
 - You will be asked to follow the restriction regarding physical activity, consumption of caffeine- and alcoholic products.
 - You are not eligible to participate if:
 - You received a therapeutic vaccine less than 4 weeks before receiving the study medication.
 - You received intra-articular (into the joint) injection therapy (e.g., corticosteroids) less than 4 weeks before receiving the study medication.
 - You have a history of tuberculosis.
 - You donated blood less than 3 months (men) or 4 months (women) before the pre-screening, or you plan to donate blood during the study.



INTEREST IN PARTICIPATING

Registration for this study only indicates your interest and does not obligate you to participate, nor us to include you as a participant.

Thank you in advance for your interest and we hope to welcome you soon for study 2600007 part 2.

SGS CPU