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**STUDY MEDICATION FOR THE TREATMENT OF THROMBO-EMBOLIC DISORDERS INCLUDING  
DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLS**

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Edegem, 18 November 2022

**Studienummer: BE-80-2100411**

Dear

We are looking for subjects for a study of study medication for the treatment of thromboembolic disorders, including deep vein thrombosis and pulmonary emboli (blocked blood vessels by blood clots).

The study consists of at least 2 cohorts of 8 persons each (each cohort consists of 2 subcohorts: a sentinel cohort of 2 persons and a main cohort of 6 persons). You can register for multiple cohorts, but only participate in 1 cohort. The study will run over a period of  $\pm$  28 weeks.

The medication is administered subcutaneously (under the skin using a needle) in this cohort.
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The study includes:

For cohort SC 1 main:

- A screening visit
- One period with a stay of 4 days and 3 nights in our unit
- 5 morning return visits
- A discharge visit

For cohort SC 2 sentinel and SC 2 main:

- A screening visit
- One period with a stay of 4 days and 3 nights in our unit
- 9 morning return visits
- A discharge visit

If you refer a family member or acquaintance who has not yet been included in our database and who has participated in a preliminary investigation, SGS will give you a gift voucher worth € 50. Please follow up yourself if you are entitled to this voucher that can only be collected join the recruitment team.

Kind regards

The recruitment team

### INCLUSION CRITERIA

- Healthy male and female
- Age: between 18 and 55 years (**inclusive**)
- BMI: between 18,0 and 32,5 kg/m<sup>2</sup>
- Non-smoker or ex-smoker for at least 12 months before screening
  - **A cotinine test will be performed during the standard screening visit (and each entry period).** This means that you have to stay out of smoky areas a few days in advance
- No medication, vitamin or homeopathy use during the last 2 weeks before the screening (in consultation with the doctor it is possible that you will continue to take certain medication during the study such as paracetamol, anti-histamines or short-term corticosteroids)
- **Latest participation (last visit in a previous study)** 4 weeks (28 days) before screening
  - **Cohort SC 1 main:** 21/11/2022
  - **Cohort SC 2 sentinel:** 28/12/2022
  - **Cohort SC 2 main:** 02/01/2023
- Contraception:
  - **Woman of non-childbearing potential:**
    - **OR** postmenopausal (= no menses for at least 12 months)
    - **OR** hysterectomy (= removal uterine)
    - **OR** bilateral ovariectomy (= removal both ovary)
  - **Male with fertile partner:**
    - **OR** use a condom + effective contraception
    - **OR** vasectomy
      - **You must bring a document to the screening to proof the procedure**
- Do not perform any sperm donations during the study until after the last visit
- Be prepared to provide a stool sample to check for blood in your stool (a test kit will be given to you at the end of the preliminary examination)
- You are not allowed to participate in contact sports or sports where you bump into an object during your participation in the study until after the final study
- You may not donate blood 56 days before screening, no plasma donation in the 7 days before screening or donate blood products during the study until after the final examination
- You are not a (family of) SGS employee directly involved in the study (unless participation is approved by the sponsor)
- No hospitalization in the last 30 days before the preliminary examination
- You did not participate in a previous cohort of this study

## TAX-FREE REMUNERATION

### **Cohort SC 1 main:**

- € 1600 for the complete study (screening included)
- € 400 for reserve volunteers (screening included)
- € 50 for the selection visit

### **Cohort SC 2 sentinel and SC 2 main:**

- € 2000 for the complete study (screening included)
- € 400 for reserve volunteers (screening included)
- € 50 for the selection visit

You will receive a reimbursement for your travel costs, which is set at € 0.3542 per km, with a maximum of 120 km (one way).

The payout of those not selected for the study and the reserves will start after D1. If you are an effective participant in the study, the payment will start after your final study. The payout period lasts ± 4 to 6 weeks.

### **ATTENTION:**

- In case of early study termination, the financial compensation can be adjusted based on the study duration as well as the reason for early termination. This decision will be taken by the SGS study team.
- You will **not** receive any payment if you test positive for illegal substances or alcohol at the selection visit.
- A cotinine test will also be performed on D-1.

## ARE YOU A RESERVE VOLUNTEER?

- You will also come in the unit on **D-1** (morning return visit and admiddion in the evening and you need to stay until approximately 2 hours after the administration of the study medication on **D1**).
- You meet all inclusion criteria and you have kept all study restrictions given at the selection visit
- You are able to participate in the entire study

## **SUBSCRIPTION**

**Do you want to subscribe? Please follow the below steps:**

### **step 1**

Mail now to

**[be.inschrijvingen@sgs.com](mailto:be.inschrijvingen@sgs.com)**

**OR**

Call now to **+32 (0)3 217 21 72**

(please only call between 8u00 – 12u00 and 13u00 - 17u00)

**The point of time you subscribed will determinate your sequence during the trial.**

### **stap 2**

Please mention below:

Study number **BE-80-2100411**

**Cohort SC 1 main OR**

**Cohort SC 2 sentinel and/or SC 2 main**

Name and surname

Date of birth

Phone number

### **stap 3**

**If your profile qualifies for the study, we will contact you as soon as possible to make an appointment for the screening visit.**

Reacting to this letter only expresses your interest and does not oblige you nor us to subscribe (or accept your request) to participate.

## COURSE OF THE STUDY

SC Dose level 1 main		
Screening		
Between Monday 21 November and Friday 25 november 2022	Screening	Standard screening visit (fasted) +/- 3h
Period 1		
Monday 19 December 2022	D-1	Morning return visit (fasted +/- 1u) and admission during the evening (+/- 18u00)
<b>Tuesday 20 December 2022</b>	<b>D1</b>	Stay in the unit : <b>administration of the study medication</b>
Wednesday 21 December 2022	D2	Stay in the unit
Thursday 22 December 2022	D3	Go home before noon
Tuesday 27 December 2022	D8	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 3 January 2023	D15	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 10 January 2023	D22	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 17 Januariy 2023	D29	Returning visit in the morning (not fasted ; +/-1u)
End of trial visit		
Tuesday 24 January 2023	EOT	Standard examination (fasted +/-3u)

SC Dose level 2 sentinel		
Screening		
Between Monday 2 January and Friday 6 January 2023	Screening	Standard screening visit (fasted) +/- 3h
Period 1		
Wednesday 25 January 2023	D-1	Morning return visit (fasted +/- 1u) and admission during the evening (+/- 18u00)
<b>Thursday 26 January 2023</b>	<b>D1</b>	Stay in the unit : <b>administration of the study medication</b>
Friday 27 January 2023	D2	Stay in the unit
Saturday 28 January 2023	D3	Go home before noon
Thursday 2 February 2023	D8	Returning visit in the morning (not fasted ; +/-1u)
Thursday 9 February 2023	D15	Returning visit in the morning (not fasted ; +/-1u)
Thursday 16 February 2023	D22	Returning visit in the morning (not fasted ; +/-1u)
Thursday 23 February 2023	D29	Returning visit in the morning (not fasted ; +/-1u)
Thursday 2 March 2023	D36	Returning visit in the morning (fasted ; +/-1u)
Thursday 9 March 2023	D43	Returning visit in the morning (not fasted ; +/-1u)
Thursday 16 March 2023	D50	Returning visit in the morning (not fasted ; +/-1u)
Thursday 23 March 2023	D57	Returning visit in the morning (fasted ; +/-1u)
End of trial visit		
Thursday 30 March 2023	EOT	Standard examination (fasted +/-3u)

SC Dose level 2 main		
Screening		
Between Monday 9JAN2023 and Friday 27JAN 2023	Screening	Standard screening visit (fasted) +/- 3h
Period 1		
Monday 30 januari 2023	D-1	Morning return visit (fasted +/- 1u) and admission during the evening (+/- 18u00)
<b>Tuesday 31 januari 2023</b>	<b>D1</b>	Stay in the unit : <b>administration of the study medication</b>
Wednesday 1 February 2023	D2	Stay in the unit
Thursday 2 February 2023	D3	Go home before noon
Tuesday 7 February 2023	D8	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 14 February 2023	D15	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 21 February 2023	D22	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 28 February 2023	D29	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 7 March 2023	D36	Returning visit in the morning (fasted ; +/-1u)
Tuesday 14 March 2023	D43	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 21 March 2023	D50	Returning visit in the morning (not fasted ; +/-1u)
Tuesday 28 March 2023	D57	Returning visit in the morning (fasted ; +/-1u)
End of trial visit		
Tuesday 4 April 2023	EOT	Standard examination (fasted +/-3u)



**Rekruteringsbrief**  
Referenced Controlled Document