

**STUDY MEDICATION FOR THE TREATMENT OF ASTHMA AND COPD**

**SGS – Clinical Research**  
Clinical Pharmacology Unit  
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Edegem, 11 Januari 2023

**Study number: BE-80-2100230**

Dear pioneer,

We are currently looking for healthy volunteers to participate in a trial with **study medication for the treatment of asthma and COPD**.

The study consists of 5 cohorts of 12 to 15 people each. You can subscribe for multiple cohorts, but you can only participate in 1. The study will take about  $\pm$  10 weeks to complete.

De studie medicatie zal worden toegediend via een inhalator (puffer)

The study medication will be administered via an inhaler (puffer)

The study consists of:

- A standard examination visit
- A spirometry test (lung function test)
- 4 periods: each with a stay of 3 days and 2 nights in our unit
- A follow-up telephone call (men only) and a visit to our unit (women only)

If you introduce a family member or acquaintance not yet registered in our database and participates in a selection visit, SGS will provide you with a voucher of **€ 50**. Please follow up whether you are entitled to a voucher which can only be collected in the offices of the recruitment team.

Kind regards,

The SGS recruitment team

## INCLUSION CRITERIA

- Healthy men and women
- Age: between 18 and 55 years (inclusive)
- BMI: between 19 and 30.0 kg/m<sup>2</sup> (inclusive)
  - Weight must be at least 50 kg
- Non-smoker or quit smoking at least 12 months before screening (6 months in case of e-cigarettes)
  - You may not have smoked more than 5 pack years: *number of cigarette packs per day x number of years that you have smoked*
  - **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**
- Not using any medication, vitamin, or homeopathic substances
- **Latest participation (visit discharge) in a clinical trial:**
  - **Cohort A: 28JAN2023**
  - **Cohort B: 01FEB2023**
  - **Cohort C: 25FEB2023**
  - **Cohort D: 01MAR2023**
  - **Cohort E: 18MAR2023**
- **Contraception:**
  - **Women:**
    - **OR** use of a good contraception method (oral contraception, hormonal IUD, contraceptive injection,...)
    - **OR** partner with vasectomy or infertile (by definition bilaterally removed testicles) partner
    - **OR** abstinence
  - **Infertile women:**
    - **OR** postmenopausal (= no menstrual period for at least 12 months)
    - **OR** hysterectomy (= removal of the uterus)
    - **OR** bilateral salpingectomy (= removal of both fallopian tubes)
    - **OR** bilateral oophorectomy (= removal of both ovaries)
    - **OR** tubal ligation
  - **Men:**
    - Must not use contraception
- Be prepared to perform a **lung function test** (spirometry) during the standard screening visit
- You must have good puncture veins
- You did not have a positive Covid-19 test in the past 2 weeks, or complications of the infection that have not been resolved within 14 days of screening
- Have not had an infection that has not yet healed in the past 7 days before screening
- No blood loss or donation (450mL) in the past 8 weeks prior to screening or administration of the study medication
- No heavy caffeine user (no more than 5 glasses/cups per day: e.g., coffee, cola, tea,...)
- No history of drug and alcohol abuse in the past 12 months
- No history of presence of asthma (including childhood asthma)

**TAX-FREE REMUNERATION**

- € 2600 for completing the entire study (including selection visit)
- € 400 for reserve volunteers (including selection visit)
- € 50 for the selection visit

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

The payment of reserve volunteers starts after D1. Effective volunteers will be paid after completion of the last visit. The payment term will take up to 4-6 weeks.

**ATTENTION:**

- In the event 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.

**ARE YOU A RESERVE VOLUNTEER?**

- You will be admitted to the unit at **D-1**, and you will stay until approximately 2 hours after the administration of the study medication to the effective volunteers on **D1** (only in period 1)
- 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 on **Thursday 12 January 2023 at 08h30** to [be.inschrijvingen@sgs.com](mailto:be.inschrijvingen@sgs.com)

**OR**

Call on **Thursday 12 January 2023 at 08h30** to **+32 (0)3 205 56 03**

*(please only call between 08h30 and 17h30)*

**Subscriptions received before 8h30 will not be registered. You cannot subscribe multiple people within the same mail. The point of time you subscribed will determinate your sequence during the trial.**

**step 2**

Please mention the below:

Study number **BE-80-2100230 Cohort A, B, C, D and/or cohort E**

Name and Surname

Date of birth

Phone number

Number of smoking years (start + end year) + number of cigarettes per day

**step 3**

On **Monday 16 and/or Tuesday 17 January 2023** we will call the **first 180 subscriptions** back between 08h and 17h.

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**

Cohort A		
<b>Screening</b>		
Between Monday 6 February 2023 and Friday 10 February 2023	Screening	Standard screening visit (fasted) +/- 3h
Tuesday 14 February 2023 <b>OR</b> Thursday 16 February 2023	Lung function test	Spirometry (+/- 1h)
<b>Period 1</b>		
Sunday 26 February 2023	D-1	Come to the unit in the afternoon
<b>Monday 27 February 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 28 February 2023	D2	Go home in the morning
<b>Period 2</b>		
Sunday 5 March 2023	D-1	Come to the unit in the afternoon
<b>Monday 6 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 7 March 2023	D2	Go home in the morning
<b>Period 3</b>		
Sunday 12 March 2023	D-1	Come to the unit in the afternoon
<b>Monday 13 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 14 March 2023	D2	Go home in the morning
<b>Period 4</b>		
Sunday 19 March 2023	D-1	Come to the unit in the afternoon
<b>Monday 20 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 21 March 2023	D2	Go home in the morning
<b>End of trial visit</b>		
Thursday 30 March 2023	VD	<b>Women:</b> Standard screening visit (lasts +/- 1h) <b>Men:</b> Follow-up phone call

Cohort B		
<b>Screening</b>		
Between Monday 13 February 2023 and Friday 17 February 2023	Screening	Standard screening visit (fasted) +/- 3h
Tuesday 21 February 2023 <b>OR</b> Thursday 23 February 2023	Lung function test	Spirometry (+/- 1h)
<b>Period 1</b>		
Thursday 2 March 2023	D-1	Come to the unit in the afternoon
<b>Friday 3 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 4 March 2023	D2	Go home in the morning
<b>Period 2</b>		
Thursday 9 March 2023	D-1	Come to the unit in the afternoon
<b>Friday 10 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 11 March 2023	D2	Go home in the morning
<b>Period 3</b>		
Thursday 16 March 2023	D-1	Come to the unit in the afternoon
<b>Friday 17 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 18 March 2023	D2	Go home in the morning
<b>Period 4</b>		
Thursday 23 March 2023	D-1	Come to the unit in the afternoon
<b>Friday 24 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 25 March 2023	D2	Go home in the morning
<b>End of trial visit</b>		
Monday 3 April 2023	VD	<b>Women:</b> Standard screening visit (lasts +/- 1h) <b>Men:</b> Follow-up phone call

Cohort C		
<b>Screening</b>		
Between Monday 6 March 2023 and Friday 10 March 2023	Screening	Standard screening visit (fasted) +/- 3h
Tuesday 14 March 2023 <b>OR</b> Thursday 16 March 2023	Lung function test	Spirometry (+/- 1h)
<b>Period 1</b>		
Sunday 26 March 2023	D-1	Come to the unit in the afternoon
<b>Monday 27 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 28 March 2023	D2	Go home in the morning
<b>Period 2</b>		
Sunday 2 April 2023	D-1	Come to the unit in the afternoon
<b>Monday 3 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 4 April 2023	D2	Go home in the morning
<b>Period 3</b>		
Monday 10 April 2023	D-1	Come to the unit in the afternoon
<b>Tuesday 11 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Wednesday 12 April 2023	D2	Go home in the morning
<b>Period 4</b>		
Monday 17 April 2023	D-1	Come to the unit in the afternoon
<b>Tuesday 18 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Wednesday 19 April 2023	D2	Go home in the morning
<b>End of trial visit</b>		
Friday 28 April 2023	VD	<b>Women:</b> Standard screening visit (lasts +/- 1h) <b>Men:</b> Follow-up phone call

Cohort D		
<b>Screening</b>		
Between Monday 13 March 2023 and Friday 17 March 2023	Screening	Standard screening visit (fasted) +/- 3h
Tuesday 21 March 2023 <b>OR</b> Thursday 23 March 2023	Lung function test	Spirometry (+/- 1h)
<b>Period 1</b>		
Thursday 30 March 2023	D-1	Come to the unit in the afternoon
<b>Friday 31 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 1 April 2023	D2	Go home in the morning
<b>Period 2</b>		
Thursday 6 April 2023	D-1	Come to the unit in the afternoon
<b>Friday 7 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 8 April 2023	D2	Go home in the morning
<b>Period 3</b>		
Thursday 13 April 2023	D-1	Come to the unit in the afternoon
<b>Friday 14 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 15 April 2023	D2	Go home in the morning
<b>Period 4</b>		
Thursday 20 April 2023	D-1	Come to the unit in the afternoon
<b>Friday 21 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 22 April 2023	D2	Go home in the morning
<b>End of trial visit</b>		
Monday 1 May 2023	VD	<b>Women:</b> Standard screening visit (lasts +/- 1h) <b>Men:</b> Follow-up phone call



Cohort E		
<b>Screening</b>		
Between Monday 27 March 2023 and Friday 31 March 2023	Screening	Standard screening visit (fasted) +/- 3h
Tuesday 4 April 2023 <b>OR</b> Thursday 6 April 2023	Lung function test	Spirometry (+/- 1h)
<b>Period 1</b>		
Sunday 16 April 2023	D-1	Come to the unit in the afternoon
<b>Monday 17 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 18 April 2023	D2	Go home in the morning
<b>Period 2</b>		
Sunday 23 April 2023	D-1	Come to the unit in the afternoon
<b>Monday 24 April 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Tuesday 25 April 2023	D2	Go home in the morning
<b>Period 3</b>		
Monday 1 May 2023	D-1	Come to the unit in the afternoon
<b>Tuesday 2 May 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Wednesday 3 May 2023	D2	Go home in the morning
<b>Period 4</b>		
Monday 8 May 2023	D-1	Come to the unit in the afternoon
<b>Tuesday 9 May 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Wednesday 10 May 2023	D2	Go home in the morning
<b>End of trial visit</b>		
Friday 19 May 2023	VD	<b>Women:</b> Standard screening visit (lasts +/- 1h) <b>Men:</b> Follow-up phone call