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	Study medication for the treatment of Influenza A (flu)	Revision : 1.0
		Date : 25JUN2019

SGS -Life Science Services

Clinical Pharmacology Unit Antwerpen
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 2060 Antwerpen
 03 217 21 72
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Study number: BE-80-1800488

Antwerp, 25 June 2019

Dear

We are currently looking for **155 healthy volunteers** to participate in a trial with **study medication for the treatment of Influenza A (flu)**.

The study consists of 7 groups of 20 people each. You can subscribe for multiple panels, but you can only participate in 1. **When registering, please indicate all possible groups which you are available for.** The study will take about 8 months to complete.

The study consists of:


- Prescreening (VS1): Information about the study + blood sample (not fasted)
- Screening visit (VS2): General examination (fasted)
- Vaccination visit: Ambulant visit (\pm 2 hours after vaccination)
- 3 retours (short visits to our unit)
- 2 telephone follow-ups
- A stay of 13 days and 12 nights in our unit
- End of trial visit
- A telephone follow-up

The screening exists out of 2 parts. You need to be present on both days to be able to participate in the entire study.

During this study the Influenza A flu virus will be given intranasal (through the nose) with the aid of a nasal spray. During your stay you will stay in quarantine (closed ward). Because of this you may **NOT** receive any visits during this stay.

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 OR **€ 50**. Please follow up whether you are entitled to a voucher which can only be collected in the ORfices OR the recruitment team.

Kind regards,
 The SGS recruitment team

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1. INCLUSION CRITERIA

- Healthy men/women
- Age: between 18 and 55 years (inclusive)
- BMI: between 19 and 32 kg/m² (inclusive)
- Non-smoker or ex-smoker (quit at least 3 months ago)
 - You are not allowed to smoke during your stay in the unit.
- Not using any medication, vitamin or homeopathic substances (with exception of Ibuprofen, Paracetamol and oral contraception)
- **Latest participation (visit discharge) in a clinical trial:**
 - **Group 3bis:** 13/02/2019
 - **Group 4:** 05/03/2019
 - **Group 5:** 08/05/2019
 - **Group 6:** 29/05/2019
- Birth control:
 - **Women:** Use of a good birth control method
 - F.e. vasectomy partner, abstinence, oral, implant, injection, spiral,...
 - **Infertile Women:** F.e. Hysterectomy, tubal ligation, postmenopausal (no menses since 12 months)
 - **Men:** If you have a fertile partner that does not use any kind of birth control, you have to use a good birth control method
 - F.e. use of a condom, vasectomy or abstinence
- Willing to not have a flu vaccine in the 2018-2019 season
- Willing to not receive any visit during your stay in the unit
- Willing to not use intranasal corticosteroids for 7 days before the screening visit (VS2)
- You did not have Influenza A (flu) 6 months before the screening visit (VS2)
- You cannot participate in this study if
 - You or the person with whom you frequently come in contact with (whether or not during the working environment) is an individual with suppression of the immune system, patients with chronic lung diseases or elders (+65 years) or people receiving chemotherapy
- You may not be an employee of SGS CPU Antwerp
- You may not be a family member or an employee of SGS CPU Antwerp

2. TAX-FREE RENUMMERATION


- **€ 4000** for completing the entire study (including selection visit)
- **€ 1000** for reserve volunteers that come in on Day-2 (including VS1 + VS2 + vaccination + retours)
- **€ 250** for back-up reserve volunteers that come for the vaccination visit, but will not be vaccinated (including VS1 + VS2 + vaccination + **travel reimbursement included**)
- **€ 120 for VS1 and VS2 (Travel reimbursement included)**
- **€ 50** for the prescreening (VS1) (**Travel reimbursement included**)

Travel reimbursement applies to effective and reserve volunteers and is set at € 0.20/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.

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3. ARE YOU A RESERVE VOLUNTEER?

- You will be admitted to the unit at D-2 until approximately 2 hours after the admission of the flu virus 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

4. SUBSCRIPTION

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

STEP 1

Mail now to be.inschrijvingen@sgs.com

OR

Call now to **+32 (0)3 217 21 72**
(please call between 8h and 17h)

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


STEP 2

Please mention the below information:
 Study number **BE-80-1800488 group 3bis, 4, 5 and/or 6**
 Name and Surname
 Date of birth
 Phone number

STEP 3

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


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

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5. COURSE OR THE STUDY

Group 3bis


Screening visit		
Thursday 26 June 2019 OR Friday 27 June 2019 OR Monday 1 July 2019	Screening 1	Only ICF + bloodsample, in the afternoon (not fasted)
Thursday 4 July 2019	Screening 2	General examination (+- 3h), morning (fasted) Dependable on the results of screening 1
Period 1		
Group 3bis: Vaccination on Monday 15 July 2019 – MORNING		
Monday 15 July 2019	Vaccination, MORNING	Ambulant, stay until +- 2 hours after the vaccination
Tuesday 16 July 2019	Day 2	Retour (only bloodsample), morning
Thursday 18 July 2019	Telephone follow-up D4	Do not come to the unit
Monday 22 July 2019	Day 8	Retour (general examination +/-2h), morning
Monday 12 August 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
OR Group 3bis: Vaccination on Monday 15 July 2019 – EVENING		
Monday 15 July 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Tuesday 16 July 2019	Day 2	Retour (only bloodsample), evening
Thursday 18 July 2019	Telephone follow-up D4	Do not come to the unit
Monday 22 July 2019	Day 8	Retour (general examination +/-2h), morning
Monday 12 August 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
OR Group 3bis: Vaccination on Tuesday 16 July 2019 - MORNING		
Tuesday 16 July 2019	Vaccination, MORNING	Ambulant, stay until +- 2 hours after the vaccination
Wednesday 17 July 2019	Day 2	Retour (only bloodsample), morning
Friday 19 July 2019	Telephone follow-up D4	Do not come to the unit
Monday 22 July 2019	Day 8	Retour (general examination +/-2h), morning
Monday 12 August 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
OR Group 3bis: Vaccination on Tuesday 16 July 2019 - EVENING		
Tuesday 16 July 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Wednesday 17 July 2019	Day 2	Retour (only bloodsample), evening
Friday 19 July 2019	Telephone follow-up D4	Do not come to the unit
Monday 22 July 2019	Day 8	Retour (general examination +/-2h), morning
Monday 12 August 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Period 2: Stay at the unit		
Monday 26 August 2019	Day -2	Come to the unit for stay at +/- 18h
Tuesday 27 August 2019	Day -1	Stay at the unit
Wednesday 28 August 2019	Day 1	Stay at the unit: Virus administration
Thursday 29 August 2019	Day 2	Stay at the unit

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Friday 30 August 2019	Day 3	Stay at the unit
Saturday 31 August 2019	Day 4	Stay at the unit
Sunday 1 September 2019	Day 5	Stay at the unit
Monday 2 September 2019	Day 6	Stay at the unit
Tuesday 3 September 2019	Day 7	Stay at the unit
Wednesday 4 September 2019	Day 8	Stay at the unit
Thursday 5 September 2019	Day 9	Stay at the unit
Friday 6 September 2019	Day 10	Stay at the unit
Saturday 7 September 2019	Day 11	Go home around 11h
Visit discharge		
Tuesday 24 September 2019	Day 28 Follow-up	Retour general examination (+/-3h)
Telephone follow-up		
Monday 23 December 2019	Telephone follow-up 6 months	Do not come to the unit

Group 4: NEW DATES


Screening visit		
Thursday 26 June 2019 OR Friday 27 June 2019 OR Monday 1 July 2019	Screening 1	Only ICF + bloodsample, in the afternoon (not fasted)
Thursday 27 June 2019 OR Friday 28 June 2019	Screening 2	General examination (+- 3h), morning (fasted) Dependable on the results of screening 1
Period 1		
Group 4: Vaccination on Tuesday 16 July 2019 – EVENING		
Tuesday 16 July 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Wednesday 17 July 2019	Day 2	Retour (only bloodsample), evening
Friday 19 July 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 24 July 2019	Day 8	Retour (general examination +/-2h), morning
Monday 12 August 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 10 September 2019	Telefonische opvolging D56	Do not come to the unit
OR Group 4: Vaccination on Wednesday 17 July 2019 – EVENING		
Wednesday 17 July 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Thursday 18 July 2019	Day 2	Retour (only bloodsample), evening
Saturday 20 July 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 24 July 2019	Day 8	Retour (general examination +/-2h), morning
Monday 12 August 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 10 September 2019	Telefonische opvolging D56	Do not come to the unit
OR Group 4: Vaccination on Thursday 18 July 2019 - MORNING		
Thursday 18 July 2019	Vaccination, MORNING	Ambulant, stay until +- 2 hours after the vaccination
Friday 19 July 2019	Day 2	Retour (only bloodsample), morning
Sunday 21 July 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 24 July 2019	Day 8	Retour (general examination +/-2h), morning

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Monday 12 August 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 10 September 2019	Telefonische opvolging D56	Do not come to the unit
Period 2: Stay at the unit		
Monday 16 September 2019	Day -2	Come to the unit for stay at +/- 18h
Tuesday 17 September 2019	Day -1	Stay at the unit
Wednesday 18 September 2019	Day 1	Stay at the unit: Virus administration
Thursday 19 September 2019	Day 2	Stay at the unit
Friday 20 September 2019	Day 3	Stay at the unit
Saturday 21 September 2019	Day 4	Stay at the unit
Sunday 22 September 2019	Day 5	Stay at the unit
Monday 23 September 2019	Day 6	Stay at the unit
Tuesday 24 September 2019	Day 7	Stay at the unit
Wednesday 25 September 2019	Day 8	Stay at the unit
Thursday 26 September 2019	Day 9	Stay at the unit
Friday 27 September 2019	Day 10	Stay at the unit
Saturday 28 September 2019	Day 11	Go home around 11h
Visit discharge		
Tuesday 15 October 2019	Day 28 Follow-up	Retour general examination (+/-3h), MORNING
Telephone follow-up		
Tuesday 14 January 2020	Telephone follow-up 6 months	Do not come to the unit

Group 5: NEW DATES


Screening visit		
Thursday 27 June 2019 OR Friday 28 June 2019 OR Monday 1 July 2019 OR Tuesday 2 July 2019 OR Wednesday 3 July 2019 OR Friday 5 July 2019 OR Monday 8 July 2019	Screening 1	Only ICF + bloodsample, in the afternoon (not fasted)
Thursday 18 July 2019 OR Friday 19 July 2019	Screening 2	General examination (+- 3h), morning (fasted) Dependable on the results of screening 1
Period 1		
Group 5: Vaccination on Tuesday 6 August – EVENING		
Tuesday 6 August 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Wednesday 7 August 2019	Day 2	Retour (only bloodsample), evening
Friday 9 August 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 14 August 2019	Day 8	Retour (general examination +/-2h), morning
Monday 2 September 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 1 October 2019	Telefonische opvolging D56	Do not come to the unit
OR Group 5: Vaccination on Wednesday 7 August 2019 – EVENING		
Wednesday 7 August 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Thursday 8 August 2019	Day 2	Retour (only bloodsample), evening
Saturday 10 August 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 14 August 2019	Day 8	Retour (general examination +/-2h), morning

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Monday 2 September 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 1 October 2019	Telefonische opvolging D56	Do not come to the unit
OR Group 5: Vaccination on Thursday 8 August 2019 - MORNING		
Thursday 8 August 2019	Vaccination, MORNING	Ambulant, stay until +- 2 hours after the vaccination
Friday 9 August 2019	Day 2	Retour (only bloodsample), morning
Sunday 11 August 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 14 August 2019	Day 8	Retour (general examination +/-2h), morning
Monday 2 September 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 1 October 2019	Telefonische opvolging D56	Do not come to the unit
Period 2: Stay at the unit		
Monday 7 October 2019	Day -2	Come to the unit for stay at +/- 18h
Tuesday 8 October 2019	Day -1	Stay at the unit
Wednesday 9 October 2019	Day 1	Stay at the unit: Virus administration
Thursday 10 October 2019	Day 2	Stay at the unit
Friday 11 October 2019	Day 3	Stay at the unit
Saturday 12 October 2019	Day 4	Stay at the unit
Sunday 13 October 2019	Day 5	Stay at the unit
Monday 14 October 2019	Day 6	Stay at the unit
Tuesday 15 October 2019	Day 7	Stay at the unit
Wednesday 16 October 2019	Day 8	Stay at the unit
Thursday 17 October 2019	Day 9	Stay at the unit
Friday 18 October 2019	Day 10	Stay at the unit
Saturday 19 October 2019	Day 11	Go home around 11h
Visit discharge		
Tuesday 5 November 2019	Day 28 Follow-up	Retour general examination (+/-3h), MORNING
Telephone follow-up		
Tuesday 4 February 2020	Telephone follow-up 6 months	Do not come to the unit

Group 6: NEW DATES

Screening visit		
Thursday 18 July 2019 OR Friday 19 July 2019 OR Monday 22 July 2019 OR Tuesday 23 July 2019 OR Wednesday 24 July 2019 OR Thursday 25 July 2019 OR Friday 26 July 2019	Screening 1	Only ICF + bloodsample, in the afternoon (not fasted)
Thursday 8 August 2019 OR Friday 9 August 2019	Screening 2	General examination (+- 3h), morning (fasted) Dependable on the results of screening 1
Period 1		
Group 6: Vaccination on Tuesday 27 August 2019 – EVENING		
Tuesday 27 August 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Wednesday 28 August 2019	Day 2	Retour (only bloodsample), evening
Friday 30 August 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 4 September 2019	Day 8	Retour (general examination +/-2h), morning

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Monday 23 September 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 22 October 2019	Telefonische opvolging D56	Do not come to the unit
OR Group 6: Vaccination on Wednesday 28 August 2019 – EVENING		
Wednesday 28 August 2019	Vaccination, EVENING	Ambulant, stay until +- 2 hours after the vaccination
Thursday 29 August 2019	Day 2	Retour (only bloodsample), evening
Saturday 31 August 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 4 September 2019	Day 8	Retour (general examination +/-2h), morning
Monday 23 September 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 22 October 2019	Telefonische opvolging D56	Do not come to the unit
OR Group 6: Vaccination on Thursday 29 August 2019 - MORNING		
Thursday 29 August 2019	Vaccination, MORNING	Ambulant, stay until +- 2 hours after the vaccination
Friday 30 August 2019	Day 2	Retour (only bloodsample), morning
Sunday 1 September 2019	Telephone follow-up D4	Do not come to the unit
Wednesday 4 September 2019	Day 8	Retour (general examination +/-2h), morning
Monday 23 September 2019	Day 28 Follow-up	Retour (general examination +/-2h), morning
Tuesday 22 October 2019	Telefonische opvolging D56	Do not come to the unit
Period 2: Stay at the unit		
Monday 28 October 2019	Day -2	Come to the unit for stay at +/- 18h
Tuesday 29 October 2019	Day -1	Stay at the unit
Wednesday 30 October 2019	Day 1	Stay at the unit: Virus administration
Thursday 31 October 2019	Day 2	Stay at the unit
Friday 1 November 2019	Day 3	Stay at the unit
Saturday 2 November 2019	Day 4	Stay at the unit
Sunday 3 November 2019	Day 5	Stay at the unit
Monday 4 November 2019	Day 6	Stay at the unit
Tuesday 5 November 2019	Day 7	Stay at the unit
Wednesday 6 November 2019	Day 8	Stay at the unit
Thursday 7 November 2019	Day 9	Stay at the unit
Friday 8 November 2019	Day 10	Stay at the unit
Saturday 9 November 2019	Day 11	Go home around 11h
Visit discharge		
Tuesday 26 November 2019	Day 28 Follow-up	Retour general examination (+/-3h), MORNING
Telephone follow-up		
Tuesday 25 February 2020	Telephone follow-up 6 months	Do not come to the unit