

# Does a combination of the flu shot and the corona vaccine offer enough protection?

ITM seeks 100 volunteers aged 65 years or older for vaccination study

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Dit is de omschrijving

## 100 volunteers wanted

The Institute of Tropical Medicine (ITM) is conducting a new vaccination study. This study will assess the safety and immune response of adults aged 65 years or older when a COVID-19 vaccine and a flu vaccine are administered simultaneously.

For this study, ITM is looking for 100 healthy adults aged 65 years or older, who were fully vaccinated against COVID-19 (Janssen/Pfizer-BioNTech/AstraZeneca/Moderna) at least 6 months ago or who did not yet receive a COVID-19 vaccine.

The vaccines have been approved and are being used in the national vaccination campaign in Belgium. They are the Janssen COVID-19-vaccin (Ad26.COVS.2.S) and two flu vaccines (Afluria Quadrivalent or Fluzone HD Quadrivalent).

[Register as a candidate.](#)

## Why this study?

Doctors and scientists want to compare the effects of the COVID-19 vaccine and the flu vaccine when administered together, versus when administered alone. In other words: How well are you protected against both COVID-19 and the flu when the COVID-19 vaccine is administered together with the flu vaccine?

## Can I participate?

- You have been fully vaccinated against COVID-19 with an approved vaccine (Janssen/Pfizer-BioNTech/AstraZeneca/Moderna) at least 6 months before the start of the study. Or you have not yet received a COVID-19 vaccine.
- You have good general health. If you have a chronic condition, it should be stable and well controlled.
- You are currently not participating in another clinical trial.

## How does the study proceed?

### 1. Screening

During the screening visit we will check whether you meet the conditions for participation in this study.

### 2. Vaccination

The vaccination period lasts about two months. On day 1, you will receive the first two injections. One of which is flu vaccine with a COVID-19 vaccine or a placebo. The next injection will be on day 29. Then you will receive either a COVID-19 vaccine or a placebo, depending on which group you are in.

- During the visits, there is also a physical examination and a blood test.
- One week after each vaccination day we will call you to check your symptoms.
- Twenty-eight days after the second vaccination day, there is a study visit with physical examination and blood sampling.
- During the entire vaccination period you will keep a symptom diary via an app.

### 3. Follow-up

- 90 days after the last vaccination we will call you again to check your symptoms.
- 6 months after the last vaccination there is a last study visit with physical examination and blood sampling.

## The study groups

All participants will be randomly assigned to one of four study groups.

	day 1	day 29
group 1	standard dose influenza vaccine + COVID-19 vaccine	placebo
group 2	standard dose influenza vaccine + placebo	COVID-19 vaccine
group 3	high dose influenza vaccine + COVID-19 vaccine	placebo
group 4	high dose influenza vaccine + placebo	COVID-19 vaccine

## Visiting schedule

The study visits always take place on weekdays between 9:00 and 15:00.

period	visit	day/week	procedures
screening	study visit 1*	day 0	physical examination + blood sampling
vaccination	study visit 2*	day 1	vaccinations (flu vaccin + COVID-19 vaccine or placebo) physical examination + blood sampling
	telephone call	day 8	
	study visit 3	day 29	vaccinations (flu vaccin + COVID-19 vaccine or placebo) physical examination + blood sampling
	telephone call	day 36	
	study visit 4	day 57	physical examination + blood sampling
follow-up	telephone call	week 16	
	study visit 5	week 28	physical examination + blood sampling

Study visits 1 and 2 can be done on the same day.

## Reimbursement

You will be reimbursed for participating in the study. This is to cover the costs related to your participation (travel expenses, time and effort). For each visit to the study center you receive €125 and for each telephone contact you receive €30.

## Interested?

- You meet the most important conditions?

- You are available at the scheduled times?

[Register as a candidate.](#)

Not sure if you are eligible? Do you have additional questions? Mail to [studies@itg.be](mailto:studies@itg.be) or call +323 345 56 70.

This study was approved by an independent central Ethics Committee.