



# PHASE III STUDY ON THE HPV VACCINE IN YOUTH FROM 9 TO 14 YEARS OF AGE

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# INTRODUCTION

**Hello, I'm Paul, the doctor in charge of this research project.**

This study is backed by a whole team of people: doctors, nurses, pharmacists, technicians ... You'll get to know all of us.



# WHAT IS THIS STUDY FOR?

## RESEARCH OBJECTIVE

We want to know how the V53 vaccine works against Human Papillomavirus.

We also want to know if your body has a better resistance after we vaccinate you.

Furthermore, we want you to know:

## WHAT IS A SAFE VACCINE?

*There have been some previous research studies with the same vaccine before this one. In this research study, we want to find the right dose to protect you while avoiding any bad effects it might have.*



## WHY INVESTIGATE THIS?

The problem with this virus is that it can cause skin and genital diseases in people.

In addition, in women, it can also cause cervical cancer.

## THE V53 VACCINE PROTECTS YOU AGAINST THIS VIRUS.

It has already been given to lots of kids—more kids than those who would fit on a whole football field.



# WHAT DO I HAVE TO DO TO PARTICIPATE?

## IF YOU WANT TO JOIN

### HERE'S WHAT YOU HAVE TO DO

For the study, we're making two groups: Group A and Group B. The only difference between them is the kind of vaccine they get. The group you get into is a surprise, it's called a random group, like heads or tails.

During the study, you visit us 5 times over a one-year period. Now I'll explain what these 5 visits are like.

#### VISIT 0

We meet up and check that your body is OK for the vaccine.

#### VISIT 1

We put you into one of the two groups and give you your first dose of the vaccine.

#### VISIT 2

We meet up again to see how you're doing. We'll ask you a few questions and do some tests.

#### VISIT 3

Hey, we're getting closer to the end of the study! We meet up again to give you your second dose of the vaccine.

#### VISIT 4

That's it. End of story. We meet up again to give you your third and last dose of the vaccine.

## VISIT ZERO

### ¡Nos conocemos!

We get to know each other. On Visit Zero we check to see if we can give you the vaccine or not. We check if your body is OK for the vaccine. If it is, you can go on to Visit 1.



## VISIT 1

### We start to work!

On Visit 1 you'll be assigned to one of the 2 groups. Then you'll get your first dose of the vaccine.

On this visit you get to meet Athena, the nurse.

## As we said... You get assigned to a group.

Depending on the group you are in, you will receive one vaccine or the other one. The injection that we actually give you is a surprise for everyone: Paul, the doctor, Athena, the nurse, and even for you.

And hey, you have to keep it secret until the end of the study.

### Group A

In this group you get 3 shots of the vaccine we are studying, called V53.

### Group B

In this group you get 2 shots of the vaccine that protects your liver + 1 saltwater shot.

## THE GROUPS

You get into either one group or the other. Your group will be a surprise. It's called a random group, like heads or tails.

Once you're assigned to a group, you get your first vaccine.

### GROUP A

#### THE VACCINE WE ARE STUDYING

First dose on day 1, second dose in month 2 and third dose in month 6.

### GROUP B

#### THE VACCINE TO HELP YOUR LIVER

First dose on day 1, second dose in month 2.

#### PLACEBO (1 SHOT)

1 saltwater shot in month 6



**Athena the nurse will give you a shot in your upper arm.**

The first vaccine is given in 3 shots; the second in 2.

We want the number of shots to be the same for both groups. To make sure they're the same, we'll be adding a third saltwater shot as your second vaccine. It's a shot that has no effect.

This saltwater shot is called a placebo.

## WHAT IS A PLACEBO?

*Placebo is a saltwater injection that has no effect on the patient. It's just like receiving an injection of water – it doesn't do anything.*

*Yet, sometimes it can have positive or negative effects. For example, when you are*

*strongly convinced you got the vaccine but in fact, they gave you the placebo. In this case, you might still feel some effects. The same ones you expected to get from the vaccine. These effects are called nocebo and placebo effects.*

## VISIT 2

### How are you doing?

Two weeks will have passed since your first visit, so we'll be seeing you again to find out how you're doing.

We'll ask you some questions and do some tests. For example, a blood test.

#### WHAT'S A BLOOD TEST?

*A blood test is a test to find out what your blood is like.*

*Athena the nurse will put a rubber band around your upper arm, she'll feel around your inner arm to find the place to extract some blood, then she'll prick you with a needle to get the blood out and put it in a test tube.*

*She'll only take about 4 teaspoons of blood – it's not much!*



## VISIT 3

### We're progressing.

At this point, it'll be two months since your first shot. We have to see you again now. If you're doing fine, we'll give you a second shot.

We still won't know what shot you've received. It's a secret, remember.



#### VISIT 4

### That's it. End of story.

In Visit 4 we will be completing the study. Six months will have passed since your first shot. If everything goes according to plan, and you are still strong and willing, Athena the nurse will give you your last shot.

#### **AFTER EACH VISIT, WE'LL ASK YOU TO STAY WITH US FOR A WHILE.**

About half an hour. When we're sure that everything's fine, and that you're healthy and strong, you can leave.

You'll only stay a while longer if you don't feel so good.

### **We'll keep in touch throughout.**

We'll be in touch with your parents all the time to make sure everything's going well.

Throughout the study we'll be phoning your parents to ask after you.

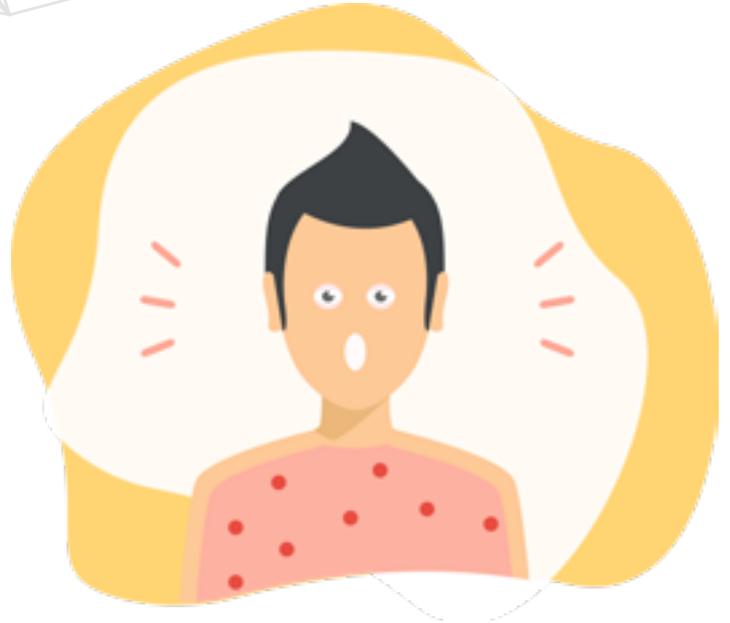


## IS IT GOING TO HURT?

### WHAT WILL I FEEL?

After getting your shot, you may notice that the spot on your arm gets red, or feels hot, swollen or that it hurts a little.

Sometimes you may feel tired, dizzy or get a headache. You may even run a fever.



If any of these happen to you, don't worry, your parents and us will know what to do to make you feel better. You'll get over this in less than a weekend.

You might have a little bruise for a day or two. The needle only hurts a bit. You'll soon get over it.

**If you notice anything else besides what we've told you, tell your parents and us right away.**

## WHAT ARE THE GOOD THINGS ABOUT PARTICIPATING?

Thanks to you, we can help other people like you to be strong and healthy.

Furthermore, you're going to help us learn about this vaccine and find out how it works.

If you are in group A, your defenses against the Human Papillomavirus may increase. If you are in group B, your defences against liver disease may increase

## WHAT DO I HAVE TO DO TO PARTICIPATE?

Read this information carefully, talk to your parents and, if you agree, talk to your doctor. If you decide to participate, sign the study papers.

Remember that you and your parents can ask whatever you want at any time. We will be there to help you.

### IS THIS MANDATORY?

*No, it is not mandatory. You and your parents are the ones who decide if you want to participate or not*

## WHAT HAPPENS IF I JOIN AND THEN WANT TO QUIT?

*You can quit the study any time you want. All you have to do is tell us. Nobody's going to get angry with you.*

*And don't forget, you can ask all the questions you want at any time.*

## WHO WILL KNOW THAT I AM PARTICIPATING IN THE STUDY?

*Your data will be on our computer, protected by password. No one is going to see your data. To keep your name secret, we give you an alias, that is, a different name. The computer is located in our centre. After the study, your personal data will be deleted.*

**If you want to see your data and have them explained to you, all you have to do is ask us.**

You should also know that this study has been reviewed previously by other doctors and researchers.

All of them thought we have prepared a good study.



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## PHASE III STUDY ON THE HPV VACCINE IN YOUTH FROM 9 TO 14 YEARS OF AGE

# THANK YOU VERY MUCH

Remember, you can ask  
questions at any time.

Thanks a lot for visiting us and reading the whole document.  
We hope you liked it and that you understood everything perfectly.

**+1 123 45 67**

*If you call this number, a member of our  
team will answer your questions.*



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