Research Study for a COVID-19 vaccine in Healthy Children and Young Adults Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing

We would like to tell you about a research study and see if you would like to take part.

You will need to read this information and then decide if you would like to be in this research study.

This research study is to find out if a new COVID-19 vaccine is safe and if it works in children and young adults.

The study doctor and nurses will explain the study and answer any questions that you have. You can circle or highlight things on this paper that you want to know more about. If you don't understand something, just ask us. It is okay to ask questions now and anytime later that you think of them.

This document is called an ***assent form***. If you have any doubts, concerns or worries please tell your study team. You can discuss this information with your family and friends if you want to.

If you are willing to be in this study, we will ask you to sign and date this assent form. If you don't want to take part that's OK – no one will be mad at you.

WHY ARE WE DOING THIS STUDY?

In 2019 a new germ (coronavirus) started making adults and children ill with a disease called COVID-19. Scientists and doctors have been working to make a vaccine that can help protect adults and children against this coronavirus. Scientists and doctors have already done some research studies in healthy adults and children and there are now a few vaccines that are allowed to be given to healthy adults and some older children.

In this research study we are looking at how well one of these vaccines (called BNT162b2) works in children like you and young adults. We want to find out if BNT162b2 can help protect children and young adults against COVID-19.

WHAT HAPPENS IN THE STUDY?

The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a disease that has spread all over the world and is affecting lots of people); finding a vaccine to prevent COVID-19 is an urgent need. To test this investigational vaccine as quickly as possible, this study will be conducted in several parts. The study will only progress if the data collected suggests it is safe to do so.

Higher levels of a protein, called troponin I, found in the blood could be an early sign of two conditions that affect the heart called myocarditis or pericarditis. If confirmed to be a reliable sign of potential myocarditis or pericarditis, testing for this protein will be done to help describe how often this may occur.

Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing. This is the part that you are being asked to participate in. This part will be carried out in 2 age groups in order to collect blood samples for potential troponin I testing. The younger age group (5 to <12 years of age) will be placebo-controlled meaning you will receive either active vaccine or placebo. The older age group (12 to <16 years of age) will be open-label meaning everyone will receive active vaccine. The children and adolescents in this part of the study will be:

- 12 to less than 16 years age, and
- 5 to less than 12 years of age.

Other parts of the study:

Phase 1 Dose Finding. Please note that this part of the study has been completed. There were 3 age groups and the study looked at up to 3 dose levels in each age group. The children in this part of the study were:

- 5 to less than 12 years of age,
- 2 to less than 5 years of age, and
- 6 months to less than 2 years of age

Phase 1 Lower Dose Evaluation. This part will be carried out in 3 age groups and will look at up to 2 dose levels. The age groups in this part of the study will be:

- 16 to less than 30 years of age,
- 12 to less than 16 years of age, and
- 5 to less than 12 years of age.

Phase 2/3 Selected Dose. In this part we will use a dose level selected from the Phase 1 Dose Finding part of the study. This step of the study will collect information from a larger number of children about the safety of the vaccine and the amount of antibodies produced by the vaccine. In this Phase, everyone will receive either active vaccine or placebo. The children in this part of the study will be:

- 5 to less than 12 years of age,
- 2 to less than 5 years of age, and
- 6 months to less than 2 years of age.

Phase 2/3 Lower Dose Evaluation. In this step of the study we will use a dose level selected from the Phase 1 part of the study. This step of the study will collect information from a larger number of children and young adults about the safety of the vaccine and the amount of antibodies produced by the vaccine. In this part of the study, everyone will receive active vaccine. The age groups in this part of the study will be:

- 16 to less than 30 years of age,
- 12 to less than 16 years of age, and
- 5 to less than 12 years of age.

Everyone will be in this research study for about 6 months.

Study Vaccines

Once the study doctor has confirmed that you meet the study requirements, you will be assigned your study vaccine.

If you are are between 5 and 11 years old, once the study doctor has confirmed you meet the study requirements, you will be randomly assigned (like flipping a coin) to receive the active study vaccine or placebo (dummy). For every 2 volunteers who receive the study vaccine, 1 volunteer will receive placebo. No one (including you, your Mom/Dad/guardian, or your doctor) can choose which option you get. If you do not receive the study vaccine you will have the opportunity to get it later in the study if you and your parents want to.

This part of the study is a 'placebo-controlled observer-blinded phase' which means that you, your parents and the study doctor will not know whether you will be receiving the study vaccine or placebo. The person who gives you the injection will know because the study vaccine and placebo do not look the same. The syringe will be covered with a label so the contents are not visible and the person that gives you the injection will not be able to talk about it. In case of urgent need, the study doctor can learn quickly whether you received study vaccine or placebo.

If you are between 12 and 15 years old, once the study doctor has confirmed that they meet the study requirements, you will receive active study vaccine.

The vaccine will be given to you through an injection into the muscle in your upper arm. Each participant will receive two injections of vaccine, approximately three weeks apart. On the days you receive your vaccine injection, you will be asked to wait with your child at the study site for at least 30 minutes for observation.

During the study:

- You will come to the research site for visits.
- We will collect a blood sample at 2 visits. The amount of blood taken at each visit will be about 5 mL (1 teaspoon).
- We will give you 1 injection at visit 1 and 1 injection at visit 2.
- We will also collect a nose swab from your nose at visit 1 and visit 2.
- You may have to come for extra visits and tests if your doctor thinks they need to see you.

You or your Mom/Dad/guardian will have to answer some questions about you on a smart phone/ APP (called an e-diary).

We will work with your mom or dad or your guardian on scheduling these visits around your activities like school. We will contact your mom or dad or guardian once or twice by phone to ask about your health.

There are 3 sorts of visits in the study. Vaccination visits, checkup visits and extra visits if you get any have a reaction after your vaccination. The table below shows you when these visits will take place and what will happen.

For the participants taking part in **Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing**, the study doctor or nurse will perform following assessment and procedures:

Summary of Planned Study Visits and Procedures for ALL Participants up to 6-Months After Vaccine 2:

Visit Number	301	302	303	304	305
Types of Visit	Clinic	Clinic	Clinic	Telephone	Telephone
Visit Description and Visit Timing	Study Vaccine 1	Study Vaccine 2	4-Day Follow-up Visit	1-Month Follow-up Visit	6-Month Follow-up Visit
Review and sign informed consent document	X				
Ask about medical history as well as date of birth, sex, race and ethnicity	X				
Measure pulse rate, respiratory rate, blood pressure, and body temperature	X	X			
Perform clinical assessment	X	X			
If you are HIV positive, ask for their latest CD4 counts and HIV viral load	X			X	X
If you are female and able to have children, you will be asked to provide a urine sample for a pregnancy test	X	X			
If needed, the study team will discuss and confirm the use of appropriate birth control with you	X	X	X	X	
Ask about medications you are currently taking		X	X	X	X
Ask about any other vaccines you have been given	X	X	X	X	X
Check you meet all the study requirements	X	X			

Visit Number	301	302	303	304	305
Types of Visit	Clinic	Clinic	Clinic	Telephone	Telephone
Visit Description and Visit Timing	Study Vaccine 1	Study Vaccine 2	4-Day Follow-up Visit	1-Month Follow-up Visit	6-Month Follow-up Visit
Take a nasal swab for the detection of virus causing COVID-19	X	X			
Collect blood sample (approximately 5 mL at each time)	X		X		
Give vaccine injection in your arm and observe for 30-min following injection	X	X			
You or your Mom/Dad/guadian will be shown how to use the e-diary (or the study team will assist you to download an app), and at Visit 301 you will be given a thermometer and a caliper (measuring device)	X	X			
You or your Mom/Dad/guadian will be asked to complete a vaccination e-diary for 7 days to record potential side effects following each vaccination	X	X			
Ask how you are feeling	X	X	X	X	X
Inform you and your Mom/Dad/guadian about which vaccine you were given at Visit 301 and Visit 302					X

Summary of Planned Study Visits and Procedures for Participants 5 to <12 Years Who Originally Received Placebo at Visit 301 and Visit 302:

Visit Number	A1	B1	C1	D1
Types of Visit	**Clinic**	**Clinic**	**Telephone**	**Telephone**
Visit Description and Visit Timing	**Study Vaccine 3**	**Study Vaccine 4**	**1-Month Follow-up Visit after Vaccine 4**	**6-Month Follow-up Visit after Vaccine 4**
Inform you and your Mom/Dad/guadian that you originally received placebo	X			
Measure pulse rate, respiratory rate, blood pressure, and body temperature	X	X		
Perform clinical assessment	X	X		
If you are HIV positive, ask for their latest CD4 counts and HIV viral load	X		X	X
If you are female and able to have children, you will be asked to provide a urine sample for a pregnancy test	X	X		
If needed, the study team will discuss and confirm the use of appropriate birth control with you	X	X	X	
Ask about medications you are currently taking	X	X	X	X
Take a nasal swab for the detection of virus causing COVID-19	X	X		
Collect blood sample (approximately 5 mL) *Blood draw is only for those who become eligible for receipt of BNT162b2 (study vaccine) or another COVID-19 vaccine according to local or national recommendations prior to Visit 303.*	X			
Give vaccine injection in your arm and observe for 30-min following injection	X	X		
Ask how you are feeling	X	X	X	X

WHAT ARE THE POSSIBLE UNCOMFORTABLE OR HARMFUL THINGS THAT COULD HAPPEN WHILE I'M IN THIS RESEARCH STUDY?

You may feel tired or embarrassed by the questions the study doctor or nurse asks you.

If you are girl and have to give a wee (urine) sample you may feel embarrassed.

When you have your nose swab taken it might be painful or your nose might bleed a bit.

When you have a blood sample taken it may:

- Hurt when the needle goes into your arm.
- Cause a red spot or bruise on your arm or your arm might feel sore.
- Make you feel dizzy.
- Cause an infection at the place where the needle went into your arm.

When you are given your vaccination it could hurt where the needles goes in your arm.

- It could also make your arm red or swollen.
- You might also feel sick or be sick.
- You might get a headache, get pains in your muscles or joints or feel tired.
- You might get chest pain, shortness of breath, or feelings of having a fast-beating, fluttering or pounding heart. You may need to come in to see the study doctor for further assessments if you have these symptoms.
- You might also get a temperature, feel shivery or cold.
- You could have an allergic reaction, which means you could have swelling of the face, or lips. Other allergic reactions may include rash, hives or itching.

You might also feel unwell in other ways. Remember to tell your parent(s) or your guardian(s) and the study doctor everything you are feeling while you are in the study including if you feel sick.

DO I NEED TO USE BIRTH CONTROL?

If you are a girl, and have started to have periods, the study doctor or nurse may test your urine to make sure you are not pregnant. The doctor or nurse will tell you if the test results show you are pregnant. Depending on the laws of your area, the study doctor or nurse may also tell your parent(s) or your guardian(s) about the results of the pregnancy test.

If you are a girl or boy who is sexually active, you must use birth control during the study and for at least 28 days after your last vaccination. If appropriate your study doctor will talk to you about this and explain your options.

If you are pregnant, planning to become pregnant or are breast feeding a baby, you cannot be in the study as there may be risks to the unborn baby or nursing baby. Nobody knows what these risks are right now.

If you think you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will have to leave the study. The study doctor may ask for

information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

If you are a boy, and you think that you may have gotten a girl pregnant while you are in the study, you must tell your study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

WHAT OTHER OPTIONS ARE THERE?

This study is for research purposes only. Your alternative is to not take part in this study.

Participation is voluntary and **you do not have to be in the study if you don't want to.**

It is your choice if you want to to be in this study or not. No one will be mad if you choose not to take part.

If you leave the study, you may be asked to come in for one last visit.

WHAT IF I HAVE QUESTIONS?

You can ask questions about the study any time. You can call the study doctor any time. If you want to ask questions about what it means to be in a research study, you or parent(s) or your guardian(s) can call [insert IRB/IEC name] (a group of people who review the study to protect your rights) at [insert IRB/IEC number].

For you to be in this study, you and your parent(s) or your guardian(s) must agree to you being in it. But it is still up to you if you *want* to do it.

Please check one box below to show whether or not you want to be in this study.

☐ Yes, I want to be in this study.

☐ No, I do not want to be in this study.

_____
Printed Name of Child/Young Person

_____ _____ _____
Child/Young Person Signature Date Time

Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the participant to the best of his or her ability to understand.
2. I have answered all questions of the participant relating to this research.
3. I believe the participant's decision to enroll or not enroll is voluntary.
4. If the participant decides to enroll, the study doctor and study staff agree to respect the

participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Printed Name of Person Obtaining Assent: _____

Signature of Person Obtaining Assent: _____ Date: _____ Time: _____