You can potentially help to protect your children—and their children—from CMV. CMV is a highly contagious virus that can stay in the body for life, be passed to unborn children during pregnancy, and lead to serious birth defects.[1,2] CMV is found in bodily fluids like saliva, so it is easily passed from kid to kid in everyday situations, such as playing on the playground or sharing food.

WHAT IS CMV?

CMV is a common and often overlooked virus with lifelong impact. For most people, the symptoms of CMV—if any—may resemble the common cold with fatigue, headache, and sore throat. Unfortunately, once CMV is in the body it's there for life, "sleeping" in the body.[1] At certain times in a person's life, such as pregnancy, CMV can reactivate.

An active CMV infection during pregnancy puts the unborn baby at risk of birth defects. These include hearing loss, vision loss, or cerebral palsy, which can lead to long-term disability or, in severe cases, death.[2]

Cerebral palsy, caused by abnormal brain development, makes muscle control difficult. Children with cerebral palsy may need special equipment to walk or may not be able to walk at all. They may also have joint problems, speech problems, or seizures.

HOW CAN WE HELP?

Over 1 in 3 11-year-olds have been infected with CMV in Canada, and this number jumps to nearly half by the time they turn 19.[3] Research shows that the number of people infected with CMV in Canada seems to be similar to the U.S. The older kids get, the more likely it is they have been exposed to CMV.

Currently, there is no approved vaccine for the prevention of CMV infection. **If we could vaccinate kids and teens against CMV, we could potentially help protect them against getting this infection before it has the chance to impact their futures—and their future children.**

Diseases do not discriminate—and neither should clinical trials

Moderna is committed to researching safe and effective mRNA-based vaccines and therapies to bring better health and living to people of all ages, sexes, and backgrounds.

Moderna keeps people at the centre of everything we do as we continue to explore what is possible through mRNA science.

Without clinical trial volunteers, researching potential new vaccines would not be possible. Together, we may help protect today's and tomorrow's children from CMV.

INTERESTED IN JOINING?

Thanks for considering this clinical trial. To learn more, and how to join, contact the clinical trial site listed below.

Clinical Trial Site Staff/Staff Name

Telephone

Email

Visit CMVibe website:

CMVibe

References:

1. Gupta M, Shorman M. Cytomegalovirus. In: StatPearls [Internet]. StatPearls Publishing; 2022. Updated August 11, 2021. Accessed April 19, 2022. https://www.ncbi.nlm.nih.gov/books/NBK459185/
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3. Bate SL, Dollard SC, Cannon MJ. Cytomegalovirus seroprevalence in the United States: the national health and nutrition examination surveys, 1988-2004. *Clin Infect Dis.* 2010;50(11):1439-1447. doi:10.1086/652438

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CMVibe

You May Help Protect Today's Children—and Tomorrow's

Learn more about the clinical trial studying a potential new vaccine that may protect kids from cytomegalovirus (CMV) infection today and, if they decide to become parents, help protect their future kids.

ABOUT THE CMVibe TRIAL

The CMVibe Trial is sponsored by Moderna. Vaccines aim to protect people against viral infections, and clinical trials are an important step in creating vaccines. A clinical trial can help researchers understand whether a vaccine not yet approved by a country's drug regulatory agency is safe and effective. The mRNA-1647 trial vaccine is a messenger RNA (mRNA) vaccine for CMV that has been studied in people 16 years of age or older in current and past clinical trials. The CMVibe Trial will look at the vaccine in kids and teens ages 9 to 15 for the first time, as well as in more females ages 16 to 25.

The purpose of the CMVibe Trial is to see which dose level (of 3 dose levels) of the mRNA-1647 trial vaccine is most effective in preventing CMV infection in people ages 9 to 15. Information from the group of participants ages 16 to 25 will help researchers compare what we see in the 9-15 age group. Dose level is the amount of trial vaccine being tested.

WHO CAN JOIN?

This clinical trial is looking for volunteers. Participants must be:

- Kids and teens ages 9 to 15 OR females ages 16 to 25
- In good health and able to follow instructions to participate in the clinical trial

The clinical trial staff will explain additional requirements and answer any questions that volunteers may have.

ABOUT THE TRIAL VACCINE

Vaccines lower the chance of getting a disease by working with the body's natural defenses. When a person gets a vaccine, their body's immune system responds and builds up protection. Normally, vaccines for viruses are made from a weakened or inactive version of the virus, but mRNA-1647 is different. It is made from an instructional molecule (mRNA) that naturally occurs in the body and helps tell your body how to make proteins. It is hoped that these proteins may help your body fight a CMV infection if you come in contact with the virus. Participants cannot become infected with CMV from getting the trial vaccine.

WHAT IS THE TRIAL VACCINE DOSE?

To understand more about the trial vaccine's effects in kids and teens ages 9 to 15, medical researchers are comparing this age group's reactions to those of participants ages 16 to 25.

✓ Participants ages 16 to 25 will get 1 dose level that has already been tested in their age group. They will get the same dose of mRNA-1647 in all 3 injections. Information from this group will help researchers compare what we see in the younger age group.

✓ Participants ages 9 to 15 will get 1 of 3 dose levels of mRNA-1647: low, medium, or high. Because this is the first time the trial vaccine is being given to this age group, we will do the trial in 3 steps to ensure maximum safety, starting with the lowest dose. Once the dose level is set for each participant, the same dose level will be given to them in all 3 injections.

The 3 dose levels being looked at are based on the dose level already looked at in adults. Participants and researchers will both know which dose the participant is getting. Every clinical trial participant will get the same level of care regardless of which dose level they are assigned to.

WHAT TO EXPECT

The total length of participation in this clinical trial is approximately 1½ years (18 months). It includes up to 12 in-person visits and 11 phone calls to check in with participants, or their parent/person taking care of them, and ask for updates on their health.

- Potential participants will have a screening visit to check whether they are eligible to join. The visit includes a wellness exam, review of medical history, and some blood tests.
- Participants will get a total of 3 injections of the trial vaccine. An injection will be given in the upper arm at 3 different visits during the first 6 months of the clinical trial.
- Participants, or their parent/person taking care of them, will enter information about how they are feeling into an app called eDiary. Clinical trial staff will show participants how to use the eDiary.

MORE ABOUT PARTICIPATION

It is important to keep a few things in mind when thinking about joining this clinical trial: The trial vaccine is still being researched.

- mRNA-1647 has already been tested for safety in people ages 16 and older.
- Participants may leave the trial at any time, without giving a reason for doing so.
- Compensation for participants' trial-related time may be provided.

Still have questions? Potential participants are encouraged to discuss the risks and benefits of participation with the clinical trial doctor at any time.