ABOUT THE CLINICAL TRIAL

Vaccines aim to safely protect people against infections, and clinical research studies are vital to creating vaccines. A clinical trial can help researchers understand whether an investigational vaccine is safe and effective. The purpose of this clinical trial is to (1) evaluate the safety and effectiveness of an investigational vaccine (a vaccine not yet approved by a country's drug regulatory agency) called mRNA-1647 against cytomegalovirus (CMV) infection in women who have not had prior CMV infection and (2) evaluate its safety in women who test positive for CMV due to prior exposure.

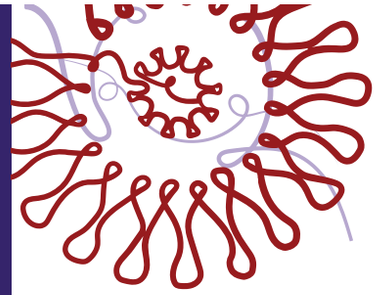
ABOUT CMV

CMV is a leading cause of birth defects around the world and is the number one infection that causes birth defects in the U.S.[1,2] CMV is a common viral infection that usually goes unnoticed or only causes mild symptoms in most people. But if a woman becomes infected with CMV while she is pregnant, she can pass the infection to her unborn baby. This can cause her child to suffer long-term disability due to birth defects, including hearing loss, or even death in very severe cases.

Currently, there is no approved vaccine against this devastating virus. That is why it is so important that we work together to make sure investigational vaccines are safe and effective to protect the most vulnerable against infection.

1 About cytomegalovirus and congenital CMV infection. cdc.gov. Updated August 18, 2020. Accessed December 7, 2020. https://www.cdc.gov/cmv/overview.html

2 Manicklal S, Emery VC, Lazzarotto T, et al. The "silent" global burden of congenital cytomegalovirus. *Clin Microbiol Rev*. 2013;26(1):86-102.



You can help create a future where we can hopefully declare victory and prevent the spread of CMV. Without people like you, researching potential new treatments and vaccines would not be possible.

Victory over CMV is only possible together

Thank you for your interest in this clinical trial. Your participation in this trial could contribute to finding a vaccine that can help protect people and generations of children to come. To learn more about this clinical trial, and how to join, contact the research clinic listed below.

Clinic/Staff Name Seattle Clinical Research Center
3216 NE 45th Pl. Suite 100
Seattle, WA 98105
Telephone (206)-522-3330 ex.2
Email recruitment@seattlecrc.com

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mRNA-1647-P301_Brochure_US_English_V3_dated23August2021

WE vs CMV

Let us be the generation that stands up to cytomegalovirus (CMV), a highly contagious viral infection that can harm an unborn child. Learn more about a research study for a potential vaccine and how you can join.

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WHO CAN JOIN THE CLINICAL TRIAL?

This clinical trial is looking for volunteers. To join this clinical trial, you must be:

- ✔ A woman between 16-40 years of age
- ✔ In good health
- ✔ Not pregnant or planning on becoming pregnant within the next 9 months
- ✔ In close contact with at least one child 5 years of age or younger for at least 8 hours a week, if age 20 or older

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

ABOUT THE MODERNA CLINICAL TRIAL VACCINE

This clinical trial is sponsored by Moderna. Moderna is studying mRNA-1647, an investigational vaccine, to understand whether it can help your immune system protect against CMV.

Vaccines lower your chance of getting a disease by working with your body's natural defenses. When you get a vaccine, your 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. The mRNA-1647 vaccine is a messenger RNA (mRNA) vaccine. This mRNA is entirely made in a laboratory and instructs your body to make small pieces of proteins.

In this case, the proteins are 2 small parts of the virus that do not cause CMV illness. The clinical trial vaccine helps the body's immune system recognize and protect itself if it comes into contact with the CMV virus in the future. You cannot become infected with CMV from receiving the clinical trial vaccine.

ABOUT THE PLACEBO

In order to understand whether the clinical trial vaccine works, medical researchers are comparing it to a placebo called saline, which is sterile salt water. A placebo does not contain the medication or vaccine.

Neither you nor the study doctor will know whether you receive mRNA-1647 or a placebo. Every clinical trial volunteer will receive the same level of quality care regardless of whether they are assigned to the clinical trial vaccine or the placebo.

ABOUT PARTICIPATION

If you are thinking about joining the clinical trial for this vaccine, it is important to keep a few things in mind:

- The clinical trial vaccine is investigational, which means that we are researching the product. We do not yet know whether it is effective in preventing CMV infection
- Throughout the clinical trial, you will be monitored closely for any side effects
- You may stop participation in the clinical trial at any time, and you do not have to give a reason for doing so
- Insurance is not needed to join this clinical trial
- Compensation for your time will be provided

Still have questions? You are encouraged to discuss the risks and benefits of participation with the study doctor at any time.

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.

WHAT TO EXPECT

The total length of participation in this clinical trial is approximately 2½ years (30 months).

- Clinical trial volunteers will have a screening visit to check whether they are eligible to participate. The visit includes a wellness exam, review of your medical history, a pregnancy test, and some blood tests
- Aside from receiving 3 injections in the upper arm over a 6-month time frame, it includes 14 total visits (1 screening visit, 5 in-person visits during the first 7 months and then in-person visits approximately every 3 months) and 21 safety phone calls or electronic (eDiary) safety check prompts over the course of the trial
- Each clinical trial volunteer has a 50% chance of receiving the clinical trial vaccine and a 50% chance of receiving a placebo—like flipping a coin

OTHER CONSIDERATIONS

- If you are planning to get a COVID-19 vaccine, it must be administered at least 28 days prior to or after receiving the investigational vaccine for this trial.
- You may get an influenza vaccine if it is administered at least 14 days prior to or after receiving the investigational vaccine for this trial.