

WHAT IS CMV?

Cytomegalovirus (CMV) is a virus that can infect people of all ages. Most people never have symptoms of CMV. This is because a healthy person's immune system can usually fight off the virus. However, the virus can cause health problems for some babies whose mothers become infected with CMV while they are pregnant.

To learn more or to see if you may qualify for the study, visit

CMVstudy.com

or contact:

Crossroads Research:

Victoria:

(361) 574-7800

Corpus Christi:

(361) 288-4668

www.3cra.com

Compensation of \$75 per visit. You may be paid up to \$1000 for completion of all study procedures.

Help us learn
how to prevent
CMV infection.



FOR WOMEN AGES 16 TO 35 WHO
ARE AROUND YOUNG CHILDREN

What is the purpose of the study?

The V160-002 study is testing a vaccine to see if it can prevent CMV infection in women who have not already been infected with CMV. This study is also testing how your body handles the vaccine, and if the vaccine is safe.

What is the study vaccine?

This study is testing a vaccine called V160. Researchers are testing the safety of the vaccine and how well it works to prevent CMV infection in women who may eventually have children. Most babies born with CMV don't have any symptoms. However, CMV can cause health problems at birth in some babies. These can include:

- vision problems
- hearing problems
- issues with the nervous system
- other health issues.

Even babies who have no CMV symptoms when they are born can develop hearing loss when they get older.

A vaccine to prevent women from getting a CMV infection may be able to stop the spread of CMV from mothers to babies. The V160 vaccine is not approved by the United States Food and Drug Administration (FDA).

Not everyone who volunteers for this study will receive the V160 vaccine. Some volunteers will get a placebo. Both the V160 study vaccine and placebo are injections, but the placebo contains no medicine. Using a placebo may let researchers learn more about how well the study vaccine works.

Who can participate in the study?

You may qualify if you are:

- A woman between the ages of 16 and 35 years old
- Around children 5 years old and younger at home or work
- Not currently pregnant

There are additional eligibility criteria that the study doctor will discuss with you.

What will happen if I join the study?

Before you can join, the study doctor will tell you a little more about the study. You will also read and sign an Informed Consent Form (ICF). This document will tell you everything that will happen in the study. You can ask the study doctor and staff as many questions as you want about the study before signing this form.

If you decide to join the study, you will first need to have some medical tests and assessments to see if you are a good fit to participate in this study.

What will I need to do in this study?

You will need to visit your study site 3 times for injections of study vaccine or placebo and up to 4 more times for follow-up. You will also need to collect and send samples of your saliva and urine each month to test for CMV. The study doctor will explain how to collect your samples. You may need to come in for more study visits if you become pregnant during the study. You should review the ICF, which will explain everything that will be expected of you during this study.

There are 3 parts in the study: the screening period, the treatment period, and the follow-up period. During the screening period, the study doctor will make sure you meet the study criteria and are a good candidate for this study. If you are eligible and choose to enroll, the total amount of time you spend in the study and the exact number of visits you have during the treatment and follow-up periods will depend mostly on when you join the study. Before you agree to volunteer, you should understand what will be required of you during the study.



SCREENING



TREATMENT



FOLLOW-UP

Can I leave the study after I start?

Taking part in this study is completely voluntary and the decision of whether to participate is completely up to you. You may leave the study at any time, for any reason. You should talk to the study doctor and staff any time about concerns and questions you have. If you decide to leave the study early, the study doctor may ask that you return to the study site for a final visit. There will be no negative impact on the care you get from the study doctor.