Use of a Live Attenuated Vaccine as an Immune-based Preventive Against COVID-19-associated Sepsis

NCT04475081

Informed Consent

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Consent to Participate in a Research Study

KEY INFORMATION FOR USE OF A LIVE ATTENUATED VACCINE REPURPOSED AS AN INNATE IMMUNE-BASED PREVENTIVE AGAINST COVID-19-ASSOCIATED SEPSIS/INFLAMMATION

Taking place at: LSUHSC Clinical and Translational Research Center (CTRC)

We are asking you to choose whether or not to participate in a research study about COVID-19. The purpose of this study is to see if giving a live (attenuated) weakened M-M-R® II vaccine (measles, mumps, rubella) to healthcare workers, first responders, and non-healthcare workers can train special white blood cells to prevent or decrease the severe inflammation associated with COVID-19 infection and sepsis. The MMR vaccine is a combination vaccine which protects against three diseases, measles, mumps, and rubella. Rubella is a contagious viral infection most often seen in children and young adults. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Please ask the research team any questions you have as you read this document. If you have questions later, the contact information for the research investigator in charge of the study is listed below. **WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**

Using common live (attenuated) weakened vaccines has been shown to provide benefits such as decreased deaths and hospital admissions due to unrelated infections in addition to the vaccine's targeted infection. It is believed that these effects are a result of training immune cells to fight a wider range of infections more effectively. This study is looking to see if the M-M-R® II vaccine can 1) produce the trained cells, and 2) prevent or decrease the severe lung inflammation associated with COVID-19 infection. The MMR vaccine is not a cure or a prevention for COVID-19. Individuals will receive the M-M-R® II vaccine or a placebo (sterile saline). Blood samples and nasopharyngeal (nose and upper throat that lies behind the nose) swabs will be collected, body mass index measured, and you will be asked to complete brief questionnaires at your first visit and 14, 30, 60 days and 6, 7 or 8 months after receiving the vaccine or placebo injection. An optional 12 month visit will be offered. Follow up questionnaires will also be done by phone call throughout the 12-month period. Your participation in this research will last 11 or 12 months. The purpose of this research is to gather information on the effectiveness of the M-M-R® II vaccine to prevent the severe inflammation associated with COVID-19 infection. The MMR vaccine is FDA-approved and is currently used in adults and children.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY?

Your participation in the study can benefit people exposed to or infected with COVID-19 by helping:

- To see if the M-M-R® II vaccine helps to produce/train immune cells that could prevent/reduce the inflammatory symptoms of COVID-19 infection and sepsis
- To see if the M-M-R® II vaccine can decrease the severe lung inflammation associated with COVID-19 infection, if exposed.

The M-M-M® II vaccine is recommended for high-risk groups.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICIPATE IN THIS STUDY?

- **YOU MAY NOT RECEIVE ANY DIRECT PROTECTION OR BENEFIT AGAINST COVID-19 EXPOSURE OR INFECTION**
- **YOU MAY NOT RECEIVE THE ACTIVE M-M-R® II VACCINE**

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to participate. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Paul Fidel, Jr., Ph.D., Principal Investigator, of the Louisiana State University Health Sciences Center School of Dentistry, Department of Oral and Craniofacial Biology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is 504-941-8425. If you have questions about your rights as a subject, or want to discuss problems, concerns or questions, or obtain information or offer input, you can contact the Chancellor of the LSU Health Sciences Center of New Orleans at (504) 568-4801.

Consent to Participate in a Research Study

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER - NEW ORLEANS
Informed Consent Form

1. **Study Title:** USE OF A LIVE ATTENUATED VACCINE REPURPOSED AS AN INNATE IMMUNE-BASED PREVENTIVE AGAINST COVID-19-ASSOCIATED SEPSIS/INFLAMMATION

2. **Performance Sites:**

LSUHSC Clinical and Translational Research Center (CTRC)
478 S. Johnson; Room 652, N.O., LA 70112

LSUHSC School of Dentistry
1100 Florida Ave
New Orleans, LA 70119

Chateau De Notre Dame Health Center
2832 Burdette St.
New Orleans, LA 70125

Wynhoven Health Care Center
1050 Medical Center Blvd.
Marrero, LA 70072

Our Lady of Wisdom Health Care Center
5600 General De Gaulle
New Orleans, LA 70131

University Medical Center LCMC
2000 Canal
New Orleans, LA 70112

3. **Investigators:**

Principal Investigator: Paul L. Fidel, Jr., Ph.D.
Address and Phone: LSUHSC School of Dentistry
Dept.of Oral & Craniofacial Biology RM 8335
1100 Florida Ave
New Orleans, LA 70119
504-941-8425

Co-Investigator: Michael Hagensee, M.D., Ph.D.
Address and Phone: LSUHSC School of Medicine
1700 Tulane Ave; RM 602
New Orleans, LA 70112
504-210-3325
24 Hour Number: 504-554-9801

Co-Investigator: Jennifer Cameron, Ph.D.
Address and Phone: LSUHSC School of Medicine
1901 Perdido St.
MEB RM 6243
New Orleans, LA 70112
504-568-2196

Co-Investigator: Hui-Yi Lin, Ph.D.
Address and Phone: LSUHSC School of Medicine
2020 Gravier St; RM 265
New Orleans, LA 70112
504-568-6083

Co-Investigator: Mary Cecile Meyaski, FNP-BC
Address and Phone: LSUHSC School of Medicine
478 S. Johnson; RM 652
New Orleans, LA 70112
504-568-2266

In case of a research injury contact: Michael Hagensee, M.D., Ph.D.
504-210-3325, 24 Hour Number 504-554-9801

4. Purpose of Study:
You are being asked to volunteer as a research participant in a research study. The purpose of this study is to determine if giving a live attenuated (weakened) MMR® II vaccine (measles, mumps, rubella) to individuals at risk for COVID-19 infection and sepsis can train white blood cells to prevent or decrease lung inflammation and infection associated with COVID-19 and sepsis, if infected. Sepsis is an imbalance in the body's chemicals produced to fight infection and triggers changes that can damage multiple organs in the body. There is increasing evidence that the use of live attenuated (weakened) vaccines (LAV) commonly given during childhood, may in addition to protection against the targeted infection, also provide beneficial non-specific effects, including reduced deaths and hospital admissions due to unrelated infections. It has been suggested that LAV effects are a result of training specialized immune cells to fight a wider range of infections more effectively. The MMR vaccine is FDA approved and a booster is recommended for susceptible individuals in high-risk groups . This is a LSUHSC study that will enroll 60 local participants.

5. Description of the Study:
Individuals 18-85 years of age in the greater New Orleans area will be eligible for the 12 month study. Subjects will be recruited from the LSUHSC, LSU Dental School, local hospitals, long-term care facilities, EMS stations, and the general community throughout the greater New Orleans area by distributing research recruitment flyers, social media postings, and by designated on-site recruitment activities conducted by study personnel within local facilities. The flyers and social media postings will have contact information for individuals to call for more information or to schedule an appointment. Additionally, subjects may be referred to the study by other participants or individuals

aware of study activities. After informed consent is obtained, the following things will be done at each study visit at the LSUHSC Clinical & Translational Research Center (LSUHSC CTRC) or collaborating performance site:

Baseline Visit- You will...

- Complete a Baseline Demographic and History Questionnaire (asking for information on your employment, medication, vaccination, and medical history)
- Have your height, weight, and BMI (body mass index) measured
- Have your vital signs (Temperature, Pulse, Respirations, Blood Pressure) taken
- Have your pulse oximetry (measurement of oxygen in the blood with a device placed on your finger) measured
  Have a blood sample collection (approximately 6 teaspoons)
- Have a blood sample by finger prick for COVID-19 antibody testing (if testing supplies are available)
- Have a urine pregnancy test if you are female and capable of becoming pregnant or think you may be pregnant
- Have a nasopharyngeal swab sample collection
- Receive either the MMR® II vaccine or placebo (an inactive substance, sterile saline) by injection just below the skin in the upper arm. Whether you get the MMR® II vaccine or the placebo (sterile saline) is determined by randomization, like the flip of a coin.

The medical history will stress information on diabetes, hypertension and heart disease with current treatments and medications. Your blood will be used to analyze your white blood cells and to test for COVID-19 and measles antibodies, as well as COVID-19 infection. Your nasal swab will be tested for COVID-19. The baseline visit will take approximately 1 hour of your time.

Some subjects will be enrolled at local facilities within the greater New Orleans area. If you are enrolled at a local facility other than the LSUHSC CTRC, you will have your baseline visit conducted on-site at the enrolling facility. If your schedule prohibits follow-up visits from being performed at the LSUHSC CTRC, you will have the option to have follow-up visits conducted at the enrolling collaborating site for your convenience. When possible, follow-up visits will be completed at the LSUHSC CTRC.

Follow-up Visits (Days 14 (+/- 2 days), 30 (+/- 2 days), 60 (+/- 4 days) following vaccination)- You will...

- Complete a Follow-up Symptom & History Questionnaire (asking about any changes in your health since your last visit)
- Have your vital signs (Temperature, Pulse, Respirations, Blood Pressure) taken
- Have your height, weight, and BMI (body mass index) measured
- Have your pulse oximetry (measurement of oxygen in the blood with a device placed on your finger) measured
- Have a blood sample Collection (approximately 6 teaspoons)
- Have a nasopharyngeal swab specimen collection

Follow-up Visit (6, 7 or 8 months following enrollment)

- Complete a Follow-up Symptom & History Questionnaire (asking about any changes in your health since your last visit)
- Have your vital signs (Temperature, Pulse, Respirations, Blood Pressure) taken
- Have your height, weight, and BMI (body mass index) measured
- Have your pulse oximetry (measurement of oxygen in the blood with a device placed on your finger) measured
- Have a blood sample collection (approximately 6 teaspoons)

Optional 12 month Follow-up Visit (You may choose not to complete this visit)

- Complete a Follow-up Symptom & History Questionnaire (asking about any changes in your health since your last visit)
- Have your vital signs (Temperature, Pulse, Respirations, Blood Pressure) taken
- Have your height, weight, and BMI (body mass index) measured
- Have your pulse oximetry (measurement of oxygen in the blood with a device placed on your finger) measured
- Have a blood sample by finger prick for COVID-19 antibody testing (if testing supplies are available)

Follow-up visits will take approximately 30 minutes hour of your time.

Monthly Telephone Follow Up – (between Day 60 follow up visit and the 12-month visit)

- Complete a Follow-up Symptom & History Questionnaire

The monthly telephone follow-up visits will take approximately 15 minutes of your time.

If at any point during the study you develop symptoms potentially related to COVID-19, you will be asked to be seen in the clinic and repeat collection of blood and nasal samples in addition to the Follow-up Symptom and History Questionnaire. You will also be asked to report if you develop any symptoms possibly related to the M-M-R® II vaccine, COVID-19 infection or a positive COVID-19 test result. If you are admitted to the hospital for COVID-19 infection, your in-patient information will be obtained through electronic medical record (EMR) when available. However, if at any time your symptoms worsen, you should go to the emergency room and not wait for the scheduled clinic visit.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

The National Clinical Trials number for this study is NCT04475081.

6. Benefits to Subjects:

It is possible that you may not receive any direct benefit at all by participating in the study. Healthcare workers are considered susceptible individuals at high risk for contracting COVID-19 infection while caring for infected patients. The MMR vaccine does not treat or prevent COVID-19

infection.

7. Risks to Subject:

The major risks associated with study participation are related to the M-M-R®II vaccine. There are few contraindications. The most frequently seen side effects associated with the M-M-R® II vaccine are mild and include dizziness, visual changes, hypotension, and fainting, soreness or rash at the injection site, a generalized body rash, fever, and swelling in the glands of the cheek or neck. More serious reactions associated with the vaccine are rarely seen and include a life threatening allergic reaction, seizures which are often associated with fever, temporary pain and stiffness in the joints, pneumonia, swelling of the brain and/or spinal cord covering, and temporary low platelet (cells that make your blood clot) count which can cause unusual bleeding and bruising. Additionally, people with serious immune system problems can develop a life threatening infection.

The risks associated with having your blood drawn include, pain or bruising at the needle site, dizziness, light-headedness, and fainting.

The risks associated with the nasopharyngeal swab collection can include gagging, pressure or discomfort as the swab is inserted into your nasal passage. You may experience minor irritation or a small amount of bleeding after the procedure.

8. Alternatives to Participation in the Study:

The alternative is not to participate.

9. Subject Removal:

The researcher may stop you from taking part in this study if at any time if it is believed to be in your best interest; if you do not follow the study procedures; or if the study is stopped. You could be taken off the study against your wishes if your health worsens; if another treatment option appears to be appropriate; or for any other cause which prevents your continuing in the study.

10. Subject's Right to Refuse to Participate or Withdraw:

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may refuse to participate or withdraw from the study at any time without jeopardizing, in any way, your medical treatment at this institution in the present or future. Information already collected about you and sent to the sponsor will still be used. Tell the researcher if you are thinking about withdrawing from the study so that you may do so safely. Should significant new findings take place during the course of the research that may relate to your willingness to continue participation,that information will be provided to you. LSUHSC employees, as well as employees from collaborating facilities refusing to participate will in no way jeopardize their employment status at LSUHSC or collaborating facilities..

11. Subject's Right to Privacy:

If the results of the study are published, the privacy of subjects will be protected, and they will not be identified in any way. Information that could be used to identify you will be kept in secure storage in the CTRC under lock and key, and information stored in the electronic database is secure and requires a username and password for access. Access to your records and data will be limited to key study team members only. A unique identification research code will be used to identify your research records in

the research database and your blood and nasopharyngeal swab samples. Your personal information may be disclosed if required by law.

12. Release of Information:
Organizations that may inspect and/or copy your study-related medical records for quality assurance and data analysis include: the Parsemus Foundation (funding agency), the LSUHSC-NO Institutional Review Board, and the doctors listed on page 1 of this consent form and their staff. While every effort will be made to maintain your privacy, absolute confidentiality cannot be guaranteed. Records will be kept private to the extent allowed by law.

13. Financial Information:
The costs of the vaccine and specimens collected are covered by the study. Any study-related and unforeseen complications must be met by the subject. The principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. There are not funds available to pay for any disability that results or for damages such as lost wages, etc. You will be paid $25.00 per clinic study visit for your participation as reimbursement for your time and travel. The money will be loaded onto a Clincard (a refillable debit card that can be used like a Visa or MasterCard) issued to you at your first study visit.

14. Signatures:
The study has been discussed with me and all my questions have been answered. Additional questions regarding the study should be directed to the investigators listed on page 1 of this consent form. If I have questions about subject's rights, or want to discuss problems, concerns or questions, or obtain information or offer input, I can contact the Chancellor of the LSU Health Sciences Center New Orleans at (504) 568-4801. I agree with the terms above, acknowledge I have been given a copy of the consent form, and agree to participate in this study. I have not waived any of my legal rights by signing this consent form.

Are you willing to have biospecimens stored for unidentified future research?

□ Yes □ No _____ _____
Subject Initials Date

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

Consent Administered by _____ Date _____

Printed Name _____

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

Signature of Reader _____ Date _____

Printed Name _____

Signature of Witness _____ Date _____

Printed Name _____