



**Recruitment Script for both email and telephonic contacts**

**Study Title:** Phase 1, Open-label, dose-ranging study to evaluate the safety, tolerability and immunogenicity of GLS-5300, administered IM and followed by electroporation in healthy volunteers

**Physician in charge of the study:** Dr. Kayvon Modjarrad

**Study Location:** Clinical Trials Center, WRAIR, 503 Robert Grant Ave, Silver Spring, MD

**Study Contact information:** Contact a staff member using e-mail: [Usarmy.detrick.medcom-wrair.mbx.clinical-trials@mail.mil](mailto:Usarmy.detrick.medcom-wrair.mbx.clinical-trials@mail.mil) or telephone: 301-319-9230

**Purpose of the study:** This is an early phase study and the reason its' being done is to test if an experimental vaccine for MERS-Co V otherwise known as Middle East Respiratory Syndrome coronavirus can protect people from getting the virus.

**What is MERs CoV?**

MERS CoV is a viral infection that was first recognized in 2012. It belongs to a family of viruses which typically cause a common cold. However, MERS CoV is more serious, and can cause people to quickly become very sick; up to 40% of those who become ill have died. MERS CoV has mainly occurred in people living in or traveling to the Arabian Peninsula, and in particular Saudi Arabia. There have been cases of travelers becoming ill, then returning to spread the illness in their home countries. For example, during the summer of 2015, a Korean businessman who traveled to Saudi Arabia became ill after returning to Korea. There were an additional 185 cases of MERS CoV infection, and even though they had access to good medical care, still had an almost 20% death rate.

This experimental vaccine has never been given to humans before, but a similar vaccine has been given for as part of other studies. This study will look at three different doses of vaccine.

The study's primary purposes are to look at safety and the ability of your body to produce antibodies, or proteins made by the body to protect against infection. This means if you were exposed to these viruses, your body would be able to more quickly respond to either prevent or lessen the effects of the infection.



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Earlier versions invalid



This new, experimental vaccine will be given into your muscle, similar to a flu shot. However, this study will use a device to give the vaccinations, called the CELLECTRA Electroporation Device. This is a hand-held, automatic electronic device, which has been used in other clinical studies for several years. The device uses a brief electrical impulse to give the vaccination, and volunteers have noted a mild muscle spasm at the injection site (similar to the reaction you get when a health provider checks your knee reflex during a physical exam).

The reason this study is using this device is that it enables safe and consistent delivery of the vaccine. It increases the amount of vaccine allowed into the cells as it 'opens the pathway' into the cells. This allows an increased uptake of vaccines compared to other delivery types. Both the increased uptake and consistency of getting the vaccine into the cells play an important role in how well a vaccine works.

### **WHAT ARE THE REQUIREMENTS TO BE IN THE STUDY?**

To be eligible for this research study, you must meet all of the following conditions:

- Healthy male or non-pregnant, non-lactating female, ages 18–50 years
- Be capable of providing informed consent
- In good health, as determined by review of your medical history, a brief physical examination, vital signs (oral temperature, heart rate, respirations and blood pressure), and clinical safety laboratory evaluations
- For females, must not be pregnant or plan to become pregnant from date of screening until at least 3 months after the last vaccination
- For heterosexual females, if sexually active, you must be at least 1 year post-menopausal or willing to use an effective method of contraception (e.g. birth control pill, diaphragm, cervical cap, intrauterine device, condom, anatomical sterility [self or partner]) from the screening visit until at least 3 months after the last vaccination
- Sexually active men who are considered sexually fertile must agree to use either a barrier method of contraception during the study, and agree to continue the use for at least 3 months following the last vaccination, or have a partner who is permanently sterile or unable to become pregnant;
- Have a Body Mass Index of less than 35 (This is a mathematical calculation based on your height and weight)





- Available for all follow-up visits and agree to complete the post vaccination memory aid

**You are not eligible to participate in this research study if any of the following apply to you:**

- History of prior infection with MERS CoV, or prior participation in a MERS CoV vaccine trial
- Have an acute or chronic medical condition affecting your heart, lungs, liver, or kidneys, noted by history, physical exam, electrocardiogram (ECG) or laboratory finding
- Obscured vaccination sites so the investigator would not be able to see vaccination reactions (e.g. tattoos or scarring covering the upper outer arms) or metal implants with 20cm (about 10 inches) of the planned vaccination site
- Positive lab test for hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) infection
- Receipt of any medications that may depress your immune system within 4 weeks of study entry
- Receipt of immunoglobulin or any blood products 4 months prior to enrollment
- Recent or ongoing participation in another clinical trial
- Receipt of licensed vaccines within 4 weeks of the first dose
- History of severe local or systemic reactions to vaccinations or a history of severe allergic reactions
- Illicit drug and/or alcohol abuse
- Unwilling to allow storage and use of some of the blood that will be collected from you during this study for future MERS CoV-related research
- Have any clinically relevant medical history or abnormality on the physical examination or certain medications considered to be significant by the study investigator
- In the opinion of the investigator, it would be unsafe for you to participate or you are unlikely to comply with the protocol





**Study Duration:** The total time volunteers must be available is up to 15 months; approximately 1 month for screening and 14 months for vaccination and follow-up.

**Study Information:**

We plan to enroll up to 75 volunteers in the study. The volunteers will be divided into 3 groups of 25. Each group will receive one injection on three separate days – study days 0, 28, 84. There are several visits after each vaccination, and they consist of a brief physical exam, collection of blood, and a review of any symptoms that have occurred. There are also three follow up phone calls.

If you are eligible and enroll in the study, you will be assigned to one of 3 groups based on the timing of your screening. You will know which group you are participating in.

There will be approximately 5 volunteers across all 3 dose groups who will be invited to participate in a Leukapheresis procedure. Please see the Leukapheresis Information sheet for more details related to this procedure.

As with any vaccine, there are risks involved. This information, along with further detail about the entire study, will be reviewed during a briefing visit done at the CTC.

**A brief schedule is below:**

- You will receive three doses of vaccine at study days 0, 28, 84
- There are 7 follow-up visits, spaced fairly evenly from the beginning Week 1 to Week 60.
- There are three follow up phone calls at day 1, week 8, and week 16.
- The final study visit is week 60.

**Compensation:**

- Volunteers will be financially compensated for their time and effort. The total amount of compensation may vary depending on the number of completed visits, but may be up to \$2180. An additional \$350 per visit will be compensated to those who are invited to participate in the Leukapheresis portion of the study.

Finally, please schedule an in-person briefing to learn more about the study!

Thank you for your time and attention to this information sheet.

