THE CAMELOT FOUNDATION INSTITUTIONAL REVIEW BOARD
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: The Fleming [FMTVDM] Directed CoVid-19 Treatment Protocol (FMTVDM).
INVESTIGATOR(S): Dr. Richard M. Fleming
PROTOCOL #: NCT04349410
SPONSOR: The Camelot Foundation

INTRODUCTION

Before you agree to participate in this research study, it is important that you read and understand the following explanation of the study. It describes the purpose, procedures, benefits, risks, discomforts and precautions associated with the study. It describes alternative treatments that are available to you and your rights as a participant, including the right to withdraw from the study at any time. It is important to understand that no guarantee or assurances can be made regarding the results of the study. It is also important to understand that refusal to participate will not influence the standard treatment you receive. This consent may contain words that you do not understand. Please ask the investigator(s) to explain any words or information that you do not understand.

It is essential that you be completely truthful regarding your health history and report any symptoms or reactions you may experience during the study. If you are not truthful, you may harm yourself by participating.

The following information will describe the research study and your role as a subject. The study doctor or study nurse will answer any questions you may have about this consent form and about the study.

This consent form may contain words that you do not understand. Please ask the study doctor(s) or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

To decide whether or not you want to be a part of this research study, you must understand enough about its risks and benefits to make an informed decision. This process is known as an informed consent. This consent form gives detailed information about the research study that will be discussed with you. Once you understand the study, you will be asked to sign this consent form if you wish to participate. Participation in this study is voluntary. Before you may participate in this research study, you will be evaluated to see if there is any reason why you should not participate. If you choose not to participate, this will in no way affect the care you receive.

Purpose of the Study

Given the current CoVid-19 (SARS-2) pandemic and the absence of an approved treatment, this study protocol is designed to determine if one of several proposed treatments is clinically beneficial

in the treatment of individuals who have tested positive for CoVid-19 and who are symptomatic as defined by the Centers for Disease Control (CDC).

Procedures

Individuals who are symptomatic and have tested positive for CoVid-19 will be admitted to hospital upon the recommendation of their physician. A series of blood tests will be obtained to assist in the treatment and monitoring of treatment of individuals undergoing treatment for CoVid-19. Prior to initiating treatment patients will undergo measurement of the severity of the corona virus disease (CoViD) using a patented nuclear imaging method (FMTVDM) to quantify the extent and severity of disease.

Following FMTVDM, an electrocardiogram and blood testing, patients will be randomly assigned to one of several treatments. As information from study sites accumulates, this may be changed from random assignment to treatment specific assignment based upon evidence of improved outcomes. Individuals that demonstrate evidence of an enhanced ImmunoThrombotic Response (ITR) associated with the body aggressively responding to the virus, will be assigned to receive treatments based upon their ITR.

Any and all treatment assignments may be altered by the patients treating physician if there are contraindications to the assigned treatment.

Following initiation of treatment, patients will be monitored per hospital protocol and the electrocardiogram and blood tests will be repeated daily.

Following 72-hours of treatment FMTVDM will be repeated to measure treatment effect. Treatment will either be continued or changed according to the measured results of treatment.

Reproductive Risks

If you are pregnant, you may not participate in this study. If you are of childbearing potential, you must have a negative pregnancy test before participation. Nursing mothers may not participate in this study. Exposure to radiotracers in pregnant or nursing mother is not recommended. If you suspect that you have become pregnant, you must notify the study doctor immediately.

Benefit to Subjects

The is no guaranteed benefit to your participation in this study. The purpose of the study is to determine the effect of these CoVid-19 treatments.

Costs

FMTVDM is being provided to the study participants without cost by the Investigator and patent owner. There is therefore no cost to participants for FMTVDM itself. All other costs are determined by the treating physician and facility where the patient is hospitalized.

Payment for Participation

There is no payment or compensation for participation in this study.

Alternatives

The alternative to participating in this study is not to participate. You are under no obligation to participate in this study.

Compensation for Injury

In the event of a physical injury resulting from your participation in this study, medical treatment is available to you. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study. The study investigator and sponsor are not providing you with a service and are not legally responsible for the care and treatment you receive.

Source of Funding

FMTVDM is being provided free of licensing fees for the purpose of this investigation. The study site and physicians involved have agreed to provide FMTVDM without cost and have agreed NOT to bill insurance of patients for any component of FMTVDM.

Confidentiality

Information from this study will remain confidential. Any and all information will be forwarded to the sponsor and investigator with identifying information redacted.

Questions

If you have additional questions during the course of this study about the research, or in the event of a research-related injury or if any other problems, you should contact your treating physician immediately.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Voluntary Participation/Withdrawal

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. Results collected from tests and exams you have undergone up to the time you withdraw consent may be used for analysis purposes.

The study doctor or the sponsor may withdraw you from this study at any time without regard to your consent if you do not follow the study instructions. In addition, if the study doctor feels that your continued participation would be undesirable for any reason, you may also be withdrawn from the study.

Participant's Initials [redacted] Page 3 of 6

Anytime participation is ended you will have end-of-study procedures, which include a review of blood pressure, pulse and breathing as well as any adverse (bad or harmful) events.

Consent

I have read the information in this consent form (or it has been read to me). The study, including its risks and benefits, has been explained to me to my satisfaction. My questions have been answered. I voluntarily consent to participate.

By signing this consent form, I agree to hold harmless the sponsor and investigator.

[redacted]
Signature of Subject Date

[redacted]
Printed name of Subject Date

[redacted]
Signature of Person Conducting Informed Consent Discussion Date

[redacted]
Signature of Treating Physician (if different from person obtaining consent) Date

----------Use the following only if applicable----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

[redacted]
Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

Participant's Initials [redacted] Page 4 of 6

PRIVACY: HIPAA Authorization Clause for Informed Consent Forms in Clinical Research

By signing this informed consent form, you authorize Dr. Richard M. Fleming (Nuclear Cardiologist) at the Camelot Foundation and the research staff to use and/or disclose your personal health information that is created or collected in the course of the research study to domestic [and foreign] regulatory agencies, its affiliates, agents, and employees, other research sites involved in the study, health care providers who provide services to you in connection with this research study, and laboratories and other individuals and organizations that analyze your health information in connection with this research study.

Your personal health information may be used or disclosed in order to conduct the research study, as necessary for your research-related treatment or payment for such treatment, to allow the above-named Institution to conduct its normal business operations, and to ensure that information relating to the study is available to the parties that need it for research purposes. The information to be used or disclosed may include, but is not limited to, your name, address, telephone number, date of birth, government-issued identification number, and medical records and charts, including the results of all tests and procedures performed during the research study.

Please be aware that after disclosure by the above-named institution, study doctor, or research staff, there is the possibility that your personal health information may be shared with other entities to which applicable privacy laws and regulation do not apply and therefore the information may no longer be protected by applicable privacy laws and regulations.

You have the right to request access to your personal health information from the above-named study doctor. To ensure proper evaluation of test results, your access to your study results may not be allowed until after the study has been completed.

This authorization does not expire. However, you may revoke this authorization by providing written notice to the above-named study doctor. If you revoke this authorization, neither the above-named institution, the above-named study doctor, the research staff, nor the above-named sponsor will be able to use or disclose your personal health information from this research study except to the extent that they have already relied on this information to conduct the research study.

Your records will be kept as confidential as possible under local, state, and federal laws. Your personal information will be redacted for your privacy.

The above-named institution, study doctor, or research staff may not condition (withhold or refuse) treating you on whether you sign this authorization. However, if you do not sign this authorization, you will not be eligible to participate in the research study.

Participant's Initials [redacted] Page 5 of 6

Authorization:

I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

[redacted]

Signature of subject Date

[redacted]

Printed name of subject

[redacted]

Signature of Person Conducting Informed Consent Discussion Date

[redacted]

Signature of Treating Physician (if different from person obtaining consent) Date