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The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study Title: Operative vs Non-Operative Management of Uncomplicated Acute Appendicitis and Acute Cholecystitis in COVID-19 Positive Patients

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KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- **Someone will explain this research study to you.**
- **You can choose whether or not to take part.**
- **You can agree to take part and then later change your mind.**
- **Your decision whether or not to participate will not be held against you.**
- **You can ask all the questions you want before you decide.**

1. INFORMATION ON THE RESEARCH

What is the purpose, procedures and duration of this study?
We invite you to take part in a research study because you have tested positive for COVID-19 and have been diagnosed with appendicitis or cholecystitis.

COVID-19, also known as Coronavirus, is an illness caused by a virus. The severity of COVID-19 is variable, and can range from patients having no symptoms to patients having severe symptoms including respiratory failure. Currently, your condition is consistent with asymptomatic or mild COVID-19.

You have also been diagnosed with appendicitis (inflammation and infection of the appendix) or cholecystitis (inflammation and infection of the gallbladder). Traditionally, these conditions are treated with antibiotics and surgical removal of the affected organ or antibiotics alone, which should resolve the acute infection and prevent further bouts of the infection.
Currently, we do not have a good understanding of what outcomes of operative and non-operative treatments are for patients with mild COVID-19. The purpose of this study is to better understand the outcomes of both operative and non-operative treatment of appendicitis and cholecystitis in the context of mild COVID-19.

If you participate, you will be randomly assigned (e.g. like flipping a coin) to receive either operative or non-operative treatment of your appendicitis or cholecystitis. You will receive care and follow-up according to a standardized protocol based on the treatment to which you have been assigned. You will be called 90 days after signing up for the study to see how you are doing and to answer several brief questions regarding any healthcare encounters (such as emergency department visits or hospital readmissions) you have had between now and that point in time.

Initial Evaluation
If you agree to take part in this study, you will be asked to sign this consent form. Your clinical condition will be treated per standard of care prior to signing this form.

Randomization
If you agree to take part in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. This means that about half of the people in this study will undergo operative management of their condition and about half of the people in this study will undergo non-operative management of their condition. Randomization will occur right after you sign the consent form and you will find out what treatment you have been assigned. You and your doctor will not be able to decide your treatment.

Treatment
Regardless of treatment assignment, you will receive antibiotics and you will receive other medications as needed to control symptoms such as pain. If you are assigned to receive surgical treatment of your disease process, your surgery will be performed in the usual manner, which is an initial minimally-invasive approach through small incisions. If needed, during the operation, a larger incision may be made if the surgeon deems it necessary. Your postoperative care will be provided as is standard for the operation you receive, and you will receive antibiotics after surgery as directed by your surgeon. If you are assigned to receive non-operative management of your condition, you will be treated with 2-3 days of intravenous antibiotics and 7 days of antibiotics by mouth. If your clinical condition does not improve or worsens, the treatment strategy will be re-evaluated and you may still require surgery (if you have appendicitis) or placement of a drainage tube into the gallbladder (if you have cholecystitis).

Follow-Up
You will be given instructions to return to follow up with your surgeon at about 2 weeks after hospital discharge. This visit is standard of care and part of your routine care and follow-up. Information about any admissions to the hospital or any subsequent procedures that may have been performed during this time will be collected. Depending on the outcomes of treatment, it is possible that you will need further management which will be provided by your surgeon based on his or her clinical judgment. At 90 days after randomization, you will be contacted to find out whether you have had any additional hospital admissions, emergency department visits, or procedures.

How long will you be in the study?
Your participation in this study will last for approximately 3 months from the date of your initial evaluation. You can choose to stop participating at any time without penalty or loss of routine care to which you are entitled. However, if you decide to stop participating in the study, it is important you talk with your doctor first.

2. ALTERNATIVES

What are the alternatives to participation in the research study?
Your participation in this study is completely voluntary. You do not have to take part in this study if you do not want to participate or if you feel uncomfortable with any part of the aforementioned process. Your choice to participate or not will have no impact on the clinical

What are possible benefits of participating in the research?
There is no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society, or science.

5. COSTS

Are there any costs to you if you participate in this study?
There is no cost to you to be in this research study. The services you will receive during this research study **are considered to be conventional routine clinical services that you would have received even if you were not participating in the research** study and will be billed to you or your health insurance plan. Examples of these routine services include: antibiotics, surgery, and clinical follow-up. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

6. PAYMENT

Are there any payments to you if you participate in this study?
There are no payments to you should you decide to participate in this study.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?
In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

If the results of this study are published, your identity will remain confidential.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions, concerns, or complaints about the research or develop a research-related problem, contact Clayton Petro, MD at 216-445-0053 during regular business hours (8am-5pm). After hours, please call the clinic operator at (216) 444-2000 or (800) 223-2273 and ask for the General Surgery resident on call, or contact the clinical team who is caring for you and they will be able to connect you with the study investigators. If you have questions about your rights as a research subject, you may contact the local Cleveland Clinic Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

If you choose to withdraw from the study, you will be followed based on the standard of care at your institution. The investigator can remove you from the study without your approval. Possible reasons could be if participation appears to be medically harmful to you, if it is discovered that you do not meet eligibility requirements, or if the study is canceled. You may refuse to be in or remove yourself from the study at any time without providing a reason, and this will not affect the standard of care you receive. To withdraw from the study, tell the principal investigator you no longer want to participate by contacting Clayton Petro, MD at 216 445-0053 or 9500 Euclid Avenue, Cleveland, Ohio 44195.