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The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Does Use of a Facemask Reduce the Risk of Aerosolization During Anesthesia Assisted Upper Endoscopic Procedures: A Randomized Controlled Pilot Trial

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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.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because we want to learn how particles are suspended into the air during your procedure. The purpose of this study is to assess the level of particles in the air during your procedure and determine if wearing a facemask reduces this number and in turn makes the procedure safer.

The endoscopic patient facemask is commonly used, but it is not known how it effects the level of particles in the air during an endoscopic procedure. We use this mask to deliver oxygen in some patients undergoing endoscopy.

If selected, you will be asked to wear a facemask during your procedure. This will not have any effect on the procedure itself and there will be no other change to the procedure you are scheduled to undergo. It will not affect your breathing, the ability of the anesthesiologist to put you to sleep, or the ability of your doctor to perform the endoscopy.

Your participation in the research will last only the time of the procedure itself which is not shortened or lengthened by this research study.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?

This research will not contribute any extra risk to your health aside from the normal risks of the procedure itself. If you do not feel comfortable wearing an endoscopy facemask while sedated for the procedure you may reasonably choose not to participate. If you choose not to participate in the research study, you may still require an endoscopic facemask during the procedure if the anesthesia staff feel it is safer for your breathing.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?

While you may not receive direct benefit from being in this study, your help may reduce the risk of infection to healthcare providers and other patients in the future. There is no extra risk this research puts towards your procedure today.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?
You can undergo your scheduled procedure as normal and measurements of particles in the air during your procedure will not be taken and you will not need to wear an endoscopic facemask unless the anesthesia doctors feel you need one for a medical reason.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

Do the researchers or institution have any conflicts of interest relating to this study?

There are no conflicts of interest to report.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

Given the heightened stress from the COVID-19 pandemic and unknown risk associated with endoscopy, this study will assess whether or not a simple facemask that is used for some patients during their endoscopy can decrease the spread of small particles into the air during the procedure.

How Many People Will Take Part in this Study?

Approximately 60 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?

If you decided to take part in this study you will undergo your endoscopy as previously scheduled without any changes to the actual procedure. Before, during, and after the procedure a device will collect information on the particles suspended in the air in the room where the endoscopy is performed. Details regarding your baseline health and demographics will be recorded for the study but your privacy will be completely protected.

A randomization process will be used to determine if you receive an endoscopy facemask during the procedure. This refers to a process that by chance will assign you to one of the study groups. Neither you nor your doctor can choose which group you are in. Your chance of receiving a facemask will be the same as a flip of a coin. After the procedure is complete there is no change to the normal post-procedure observation and discharge process that occurs for all patients.

If you should decide to participate in the study, we do not expect the length of your procedure to be affected by your participation.

How will my data be used?

Your data will be used to assess how microscopic particles are generated in the air during the procedure. No information will be distributed to other providers or other institutions. No data will be able to be tied directly back to you.

Will I be notified of the results of the tests/studies on my samples?

The study described is for research purposes only. It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. Therefore, you will not receive results from these research study. You will receive the results of your endoscopy whether you participate in this research study or not.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

The alternative to participating in this study is to proceed with your previously scheduled procedure with no measurements of the particles in the air during the endoscopy. Your baseline health and demographics will not be recorded for the study.

3. RISKS

What are the risks of participating in the research study?

This study will not increase the risk of your procedure in any way.

Confidentiality Risks

If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

4. BENEFITS

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

There is no cost to you to be in this research study.

6. PAYMENT

Are there any payments to you if you participate in this study?

There is not payment to you for being part of this research study.

7. PRIVACY AND CONFIDENTIALITY

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

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing.

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If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already

9. QUESTIONS

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

If you have any questions or concerns about the research, or develop a research-related problem, you should contact.

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During non-business hours, weekends and holidays, please contact the GI faculty on call at (216)444-2200. If you have questions about your rights as a research subject, you should contact the 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.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date