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Get the latest public health information from CDC: <https://www.coronavirus.gov>.

Get the latest research information from NIH: <https://www.nih.gov/coronavirus>.



Trial record **1 of 1** for: NCT04610294

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Operating Room Air Filtration/Sterilization



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT04610294

[Recruitment Status](#) ⓘ : Not yet recruiting

[First Posted](#) ⓘ : October 30, 2020

[Last Update Posted](#) ⓘ : December 11, 2020

See [Contacts and Locations](#)

Sponsor:

The Cleveland Clinic

Information provided by (Responsible Party):

The Cleveland Clinic

[Study Details](#)

[Tabular View](#)

[No Results Posted](#)

[Disclaimer](#)

[How to Read a Study Record](#)

Study Description

Go to

Brief Summary:

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Determine whether operating room air filtration and sterilization with the Aerus system reduces a composite of serious surgical site infections, infection-related complications, and death within 30 days after surgery.

Condition or disease ⓘ	Intervention/treatment ⓘ
Non-cardiac Surgery	Device: Functioning Aerus air filtration/sterilization Device: Deactivated Aerus air filtration/sterilization

Detailed Description:

The investigators primary goal is thus to determine whether filtering and sterilizing operating room air reduces a composite of serious surgical site infections, infection-related complications, and death within 30 days after surgery. The investigators will determine the effect of air filtration and sterilization on serious surgical site infections, and on the cost of care. infections, and on the cost of care.

Study Design

Go to

[Study Type](#) ⓘ :

Observational

[Estimated Enrollment](#) ⓘ :

86639 participants

[Observational Model:](#)

Case-Crossover

[Time Perspective:](#)

Prospective

[Official Title:](#)

Operating Room Air Filtration/Sterilization and Surgical Site Infection: A Randomized Multiple Cross-over Cluster Trial

[Estimated Study Start Date](#) ⓘ :

January 2021

[Estimated Primary Completion Date](#) ⓘ :

January 2024

[Estimated Study Completion Date](#) ⓘ :

June 2024

Resource links provided by the National Library of Medicine



[Genetic and Rare Diseases Information Center](#) resources:

[Oculocerebral Syndrome With Hypopigmentation](#)

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[U.S. FDA Resources](#)

Groups and Cohorts

Go to

<u>Group/Cohort</u> ⓘ	<u>Intervention/treatment</u> ⓘ
<p>Aerus air sterilization</p> <p>Aerus air sterilization system will be used in an operating room, in addition to routine room air filtration</p>	<p>Device: Functioning Aerus air filtration/sterilization</p> <p>Two units of Aerus air sterilization system will be used in each operating room, and each will be set to "high." Units used for the trial will be modified internally to be active and will be sealed to prevent operating room personnel from opening the system and determining a unit's status.</p>
<p>Conventional air handling</p> <p>Only routine room air filtration will be used in an operation room.</p>	<p>Device: Deactivated Aerus air filtration/sterilization</p> <p>Two units of Aerus air sterilization system will be used in each operating room, and each will be set to "high." Units used for the trial will be modified internally to be inactivated and will be sealed to prevent operating room personnel from opening the system and determining a unit's status. Units will be inactivated by removing the activated carbon, high-efficiency particulate filter, and ionization chamber. However, the fan will remain active as will the "run" lights.</p>

Outcome Measures

Go to

Primary Outcome Measures ⓘ :

1. Composite outcome of postoperative complications [Time Frame: 30 days after surgery]
A composite of mortality, major surgical site infection, and healing-related wound complications

Secondary Outcome Measures ⓘ :

1. Serious surgical site infection [Time Frame: 30 days after surgery]

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Deep or organ-space surgical site infection will be evaluated by analysis of International Classification of Disease revision 10 (ICD-10) diagnosis codes

2. Cost-of-care [Time Frame: 30 days after surgery]

Our economic analysis will estimate the cost-effectiveness ratio, defined as the difference in average total hospital costs divided by the difference in the proportion with any of the components of the composite, and expressed as average cost per 1 percent improvement in the composite outcome.

Eligibility Criteria

Go to

Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Sampling Method:

Probability Sample

Study Population

The trial will take place in the adult operating rooms of the Cleveland Clinic Main Campus, specifically ORs 1-25 in E and 28-38 in H, 40-50 in G, and J operating rooms. Because of the cohort design, all patients who have surgery in these operating rooms will be included.

Criteria

Inclusion Criteria:

- All patients in designated adult operating rooms

- American Society of Anesthesiologists physical status 1-4.
- Surgery lasting at least 1 hour.

Exclusion Criteria:

- patients with present-on-admission infections

Contacts and LocationsGo to **Information from the National Library of Medicine**

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT04610294***

Contacts

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Contact: Mauro Bravo, MD 216-636-9449 bravom2@ccf.org

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Principal Investigator: Daniel I Sessler, MD

Sponsors and Collaborators

The Cleveland Clinic

Investigators

Principal Investigator: Daniel I Sessler, MD The Cleveland Clinic

More InformationGo to

Responsible Party:

The Cleveland Clinic

ClinicalTrials.gov Identifier:

[NCT04610294](#) [History of Changes](#)

Other Study ID Numbers:

20-656

First Posted:

October 30, 2020 [Key Record Dates](#)

Last Update Posted:

December 11, 2020

Last Verified:

December 2020

Studies a U.S. FDA-regulated Device Product:

No