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

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Operating Room Air Filtration/Sterilization

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

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Brief Summary:

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

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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

U.S. FDA Resources

Groups and Cohorts

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Group/Cohort	Intervention/treatment
Aerus air sterilization Aerus air sterilization system will be used in an operating room, in addition to routine room air filtration	Device: Functioning Aerus air filtration/sterilization 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.
Conventional air handling Only routine room air filtration will be used in an operation room.	Device: Deactivated Aerus air filtration/sterilization 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.

Outcome Measures

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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]

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 Locations

Go 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

Contact: Roberta Johnson 216-444-9950 johnsor13@ccf.org

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

Locations

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Cleveland Clinic

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Contact: Roberta Johnson 216-444-9950 johnsor13@ccf.org

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

Principal Investigator: Daniel I Sessler, MD

Sponsors and Collaborators

The Cleveland Clinic

Investigators

Principal Investigator: Daniel I Sessler, MD The Cleveland Clinic

More Information

Go 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