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Official title: Clinical Study Protocol

NCT number: NCT04399005

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Protocol

Study title： Effectiveness between daily and after-each-case room disinfection of the endoscopy unit during the COVID-19 pandemic.

Approval date: May 21, 2020

Affiliation: The First Affiliated Hospital of Zhejiang Chinese Medical University.

Study description:

Brief Summary: The aim of our study was to evaluate the difference of effectiveness between daily and after-each-case room disinfection in the endoscopy unit during the COVID-19 pandemic.

Detailed Description: This study divided into two groups: daily and after-each-case room disinfection groups. Each group was again subdivided into sedation and non-sedation gastroscopy, and with or without ventilation operation room.

Samples were collected as follows: for air sample of the operation unit, a six-stage sieve percussion air sampler (airflow rate: 28.3L/min; sampling time, 4 min) was used; for workstation mouse, a sterile cotton was used to wipe the surface of the mouse; and for the isolation gown of the endoscopist, control panel buttons, and bed headboard of the patient, a contact plate was used.

Study Time:
Start: May 25, 2020
Primary Completion: June 5, 2020
Study Completion: June 10, 2020

Eligibility criteria:

Inclusion Criteria: All the cases received gastroscopy.

Exclusion Criteria: High-risk personal through epidemiological history, symptoms, body temperature, COVID-19 virus nucleic acid test, and chest computed tomography scan.

Arms and Interventions:

Arms:
Daily room disinfection: The room disinfection after completing eight non-sedation gastroscopies or four sedation gastroscopies.
After-each-case room disinfection：The room disinfection performed after completing the examination of each patient.

Assigned Interventions:
Daily room disinfection: The room disinfection after completing eight non-sedation gastroscopies or four sedation gastroscopies (Room disinfection: Room disinfection was defined as cleansing and disinfection of the surface of the facility, endoscopist's isolation gown, and air in the endoscopy room after the examination. Specifically, sanitizing wipes containing quaternary ammonium salt, alcohol, and interfacial activator were used to wipe the surfaces and the air disinfection machine was switched on for 30 min continuously).

After-each-case room disinfection：The room disinfection performed after completing the examination of each patient (Room disinfection: Room disinfection was defined as cleansing and disinfection of the surface of the facility, endoscopist's isolation gown, and air in the endoscopy room after the examination. Specifically, sanitizing wipes containing quaternary ammonium salt, alcohol, and interfacial activator were used to wipe the surfaces and the air disinfection machine was switched on for 30 min continuously).

Outcomes:
Primary Outcome Measure:
Qualified rate of room disinfection: The samples of workstation mouse, control panel buttons and patient‘s bed headboard greater than 10 CFU/cm^2, samples of endoscopist's isolation gown greater than 200 CFU/100cm^2, and samples of operation unit air greater than 500 CFU/m^3 are deemed as an unacceptable level of bioburden.

The number of colony-forming units (CFU): The number of colony-forming units (CFU) of the sample of operation unit air, workstation mouse, endoscopist's isolation gown, control panel buttons, and patient‘s bed headboard.

Statistical analysis:
Continuous variables with a non-normal distribution or ordinal variables are expressed as median (the lower four quantiles, the upper four quantiles). Categorized variables are summarized as counts and proportions. Continuous categorical variables were compared using the Wilcoxon signed-rank test (abnormal distribution), whereas categorical variables were compared using the Fisher exact test or chi-squared test.