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Can a rapid screening strategy improve infection control in critically ill patients?

Submission date
31/01/2019

Recruitment status
No longer recruiting

Registration date
11/03/2019

Overall study status
Completed

Last Edited
05/09/2022

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Current microbiologic culture methods have proved to be slow and cumbersome to support the early and adequate implementation of standard precautions and contact precautions for critically ill patients colonized with multiresistant bacteria. This study aims to compare the effectiveness of a rapid screening strategy composed of a “Loop-mediated isothermal AMPlification” (LAMP) assay targeting the main multiresistant bacteria, with the currently used routine diagnostic method to implement early, adequate and individualized preventive measures in the critical care setting.

Who can participate?
This study will include all patients admitted in the Critical Care Units of Geneva University Hospitals from April 2019 to May 2021.

What does the study involve?
The study will add a novel screening strategy to cultures currently used in the surveillance program of resistant bacteria (ESBL and CPE). The addition of these screening methods aims to accelerate this surveillance and thereby the implementation or discontinuation of contact precautions.

What are the possible benefits and risks of participating?
Expected benefits from this study are a faster implementation of contact precaution when new carriers are detected during the weekly screening, and faster discontinuation of pre-emptive contact precautions when high-risk patients are negative during the targeted screening.

Where is the study run from?
The study run from Geneva University Hospitals

When is the study starting and how long is it expected to run for?
From April 2019 to October 2020.

Who is funding the study?
This study is funded by the Swiss National Science Foundation.

Who is the main contact?
The main contact and principal investigator is Dr. Stephan Harbarth (stephan.harbarth@hcuge.ch).

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018-00329

Study information

Scientific Title
A quasi-experimental interventional study to evaluate the impact of a rapid screening strategy in improving nosocomial ESBL and CPE control in critically ill patients

Study objectives
A rapid screening strategy based a “Loop-mediated isothermal AMPlification” (LAMP) assay targeting the main ESBL-PE/CPE accelerates the implementation of adequate and individualized preventive measures in the critical care setting, compared to the currently used routine diagnostic methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
In agreement with the president of the Ethics Committee Geneva (8, Rue Adrien Lachenal, 1207 Geneva; +41 (0) 22 546 51 01; ccer@etat.ge.ch), the study design will be modified for a quasi-experimental study without cross-over as a quality improvement project that does not require informed consent, nor ethical approval.

Study design
Quasi-experimental study without control groups, non-randomised

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Infection by ESBL or CPE bacteria

Interventions
This quasi-experimental study will alternate two 12-months intervention and control periods, and a 2-months wash-out period in-between. During the intervention period, a novel ESBL/CPE screening strategy will be processed in parallel of conventional methods, during the surveillance program established in the ICU routine to support ESBL and CPE control. The novel ESBL/CPE screening strategy will include the Loop-Mediated Isothermal Amplification (LAMP) eazyplex SuperBug CRE assay (AxonLab, UK), a qualitative genotypic test covering ESBLs and

carbapenemases of the CTX M-1 and CTX M-9 families, VIM, NDM, KPC families, and OXA-48 (-48, -181). Visualization of results is provided in this assay through real-time fluorescence measurement of a fluorescent dye bound to double stranded DNA using the GENIE® II instrument. As a basis, the LAMP technology has already proved to be robust, cost-effective, real time, and performant for detecting ESBLs and carbapenemases on screening isolates. No follow-up is planned in this interventional study.

Intervention Type
Device

Primary outcome measure
Unnecessary pre-emptive isolation-days will be determined using Turn-Around-Times for ESBL /CPE screening and work up, with the help of computerized laboratory databases and a specific tool integrated into the electronic patient file, informed in real time by patient dedicated nurses. This outcome will be measured for all high-risk patient with a negative result for ESBL and CPE on a targeted screening at admission, at the time of discontinuation of pre-emptive isolation.

Secondary outcome measures
1. Time between patient screening and implementation of contact precaution of previously unknown ESBL-PE and CPE carriers will be determined using Turn-Around-Times for ESBL/CPE screening and work up, with the help of computerized laboratory databases and a specific tool integrated into the electronic patient file, informed in real time by patient dedicated nurses. This outcome will be measured for all patients newly positive for ESBL and CPE on a weekly screening, at the time of implementation of contact precaution.
2. Adjusted incidence-density ratio of nosocomial ESBL/CPE acquisition will be determined using surveillance data prospectively collected by infection control nurses. This outcome will be measured monthly.

Overall study start date
01/01/2018

Completion date
31/10/2020

Eligibility

Key inclusion criteria
All patients admitted to the Intensive Care Units during the study period

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

101 patients with unneeded isolation measures in both periods.

Key exclusion criteria
N/A

Date of first enrolment
01/04/2019

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
Geneva University Hospitals
Rue Gabrielle-Perret-Gentil 4, 1205 Genève
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Sponsor information

Organisation
Hôpitaux Universitaires de Genève

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Sponsor type
University/education

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Research organisation

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Dissemination of this interventional study will be primarily achieved by a publication in a peer-reviewed journal, in December 2021. The study results will also be presented at IPC conferences.

Intention to publish date
01/05/2022

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study, as well as the "R code" used for analysis will be available upon request from Stephan Harbarth (stephan.harbarth@hcuge.ch). These data will be available during 3 years, in excel forms after anonymisation and "R scripts", from the 31.05.19, to the 31.05.2022. Anonymization will be achieved by the destruction of the code (separate Excel file). Without this code, the data stored cannot be crossed to identify any patient and are thus considered as anonymized. As data will be anonymized, consent is not required from patients. These Excel forms will be provided by mail.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/06/2022	08/06/2022	Yes	No
Protocol file		05/09/2022	05/09/2022	No	No