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Patient isolation strategies for extended spectrum beta lactamase (ESBL) carriers in medical and surgical hospital wards

Submission date
24/01/2014

Recruitment status
No longer recruiting

Registration date
06/02/2014

Overall study status
Completed

Last Edited
14/03/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
About 30% of all healthcare-associated infections are caused by bacteria called Enterobacteriacae. Extended-spectrum beta-lactamase (ESBL) producers are a group of Enterobacteriaceae which are resistant to a number of antibiotics. The rapidly increasing prevalence of ESBL-producers in Europe is a cause for concern. To isolate or not to isolate patients with ESBL-producing Enterobacteriacae is currently one of the most controversial questions in the field of infection control (IC). Isolation measures may be associated with increased costs and side effects for the patient such as depression and reduced contact with attending physicians. Standard precautions (SP) may be as effective for limiting the spread of ESBL, if the hand hygiene procedures are followed. Adding isolation measures for the rapidly increasing number of patients colonized with ESBL should be more evidence based. The aim of this study is to determine the additional effects of isolation measures compared to SP on the frequency of getting infected by ESBL-producing Enterobacteriacae.

Who can participate?
Hospitals with adult medical and surgical wards where ESBL-producing Enterobacteriacae infection rates are high

What does the study involve?
The study involves two different infection control strategies (standard precautions [SP] and contact isolation [CI]). All participating hospital wards adopt both strategies for a period of 12 months each with a break of one month between the two study periods, with the order that they adopt the two strategies being randomly allocated. During the SP strategy for all patients hand hygiene is consistent with the World Health Organizations (WHOs) Five Moments recommendations. Clean gloves and gowns/aprons are used for all interactions that involve potentially infectious procedures. This strategy represents the current standard of care and all patients are subjected to this infection control strategy on wards in the SP phase of the trial. During the CI strategy all patients who are known to be infected with ESBL before admission are cared for using CI, preferably in a single room or in a shared room with patients who are infected with the same organism. If isolation in a single room or a shared room with patients infected

with the same organism is impossible, gloves and gowns/aprons are used for all interactions with the patient or the patients environment in a shared room. Hand hygiene is performed according to WHO's Five Moments.

What are the possible benefits and risks of participating?
The overall benefit of the study is evidence for hospitals across Europe to use (or not to use) isolation measures for patients colonized with ESBL-producing Enterobacteriaceae. Participating wards have the benefit of an intensive supervision by IC professionals in order to have good quality in care. The study involves a minimal risk of harm to patients.

Where is the study run from?
1. Charité -Universitätsmedizin Berlin (Germany)
2. Hospital Ramón y Cajal (Spain)
3. Hopitaux Universitaires de Geneve (Switzerland)
4. Universitair Medisch Centrum Utrecht (The Netherlands)

When is the study starting and how long is it expected to run for?
January 2014 to December 2017

Who is funding the study?
The study is funded by the European Commission, DG Research

Who is the main contact?
1. Prof. Petra Gastmeier
2. Dr Friederike Maechler

Study website
http://www.r-gnosis.eu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FP7-HEALTH-2011-SINGLE STAGE - N°282512

Study information

Scientific Title
Resistance of Gram-Negative Organisms: Studying Intervention Strategies: Work Package 5

Acronym
R-GNOSIS WP5

Study objectives
If all ESBL-carriers are identified, contact isolation will not reduce ESBL incidence densities of ESBL-acquisition among patients in medical and surgical wards when compared to standard precautions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Charité University Medicine Berlin, Germany, 25/04/2013, ref: EA1/323/12
2. University Medical Center Utrecht, Netherlands, 05/09/2013, ref:WAG/om/13/069083
3. University of Geneva, Switzerland, 01/10/2013, ref:CER 13-187
4. Hospital Ramon y Cajal-SERMAS, Spain, 21/10/2013

Study design
Cluster-randomized controlled study with cross-over design

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Nosocomial transmission of ESBL-producing Enterobacteriaceae

Interventions
Two different interventions:
1. Contact Isolation (CI) according to Centers for Disease Control and Prevention (CDC) /Healthcare Infection Control Practices Advisory Committee (HICPAC). Management of multidrug-resistant organisms in healthcare settings, 2006.
2. Standard Precautions (SP): Indications and technique for hand hygiene consistent with those recommended by the WHOs 'Five Moments'. Clean gloves and gowns/aprons for all interactions that involve potentially infectious procedures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
ESBL acquisition rate per 1,000 patient days. This will be measured at the end of each intervention period. Isolates will be analysed microbiologically and acquisition of ESBL-carriage will be defined as recovery of ESBL isolates from clinical and/or screening specimens >3 days after hospital admission (admission day = day 1) from patients with negative admission screening results.

Secondary outcome measures
1. New events of nosocomial ESBL infections: New events of nosocomial ESBL infections will be obtained by a continuous surveillance on the participating wards according to the Centers for Disease Control and Prevention (CDC) definitions for HAI.
2. Episodes of hand hygiene and use of gloves and gowns/aprons by healthcare workers during patient care: will be assessed in all participating wards for both intervention periods by novel electronic counting devices integrated into alcoholic handrub dispensers as well as by direct observations performed by trained monitors using a standardized observation procedure in months 3, 9, 16 and 22.
3. The antibiotic use of the wards will be collected monthly, preferably in defined daily dose (DDD) per 1000 patient-days.
4. Alcohol-based handrub consumption: Data of total handrub consumption on the ward will be obtained by the end of each intervention period.

Overall study start date
06/01/2014

Completion date

31/12/2017

Eligibility

Key inclusion criteria
Peripheral medical and surgical wards

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20 wards in Europe (Germany, The Netherlands, Spain and Switzerland) with approximately 40,000 patients

Total final enrolment
38357

Key exclusion criteria
1. Haematological wards
2. Oncologic wards
3. Transplant wards
4. Paediatric wards

Date of first enrolment
01/02/2014

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
Germany

Netherlands

Spain

Switzerland

Study participating centre

Charité -Universitätsmedizin Berlin
Berlin
Germany
12203

Study participating centre
Hospital Ramón y Cajal
Spain
-

Study participating centre
Hopitaux Universitaires de Geneve
Switzerland
-

Study participating centre
Universitair Medisch Centrum Utrecht
Netherlands
-

Sponsor information

Organisation
University Medicine Berlin (Germany)

Sponsor details
Institute of Hygiene, Charité
Hindenburgdamm 27
Berlin
Germany
12203

Sponsor type
University/education

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Government

Funder Name
European Commission, DG Research

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2020	10/08/2020	Yes	No
Other publications	Post hoc subgroup analysis	13/03/2023	14/03/2023	Yes	No