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Influence of sanitizing methods on healthcare associated infections: comparison between traditional and innovative probiotic-based approaches

Submission date
09/06/2016

Recruitment status
No longer recruiting

Registration date
14/06/2016

Overall study status
Completed

Last Edited
10/07/2023

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
Healthcare associated infections (HAIs) are a huge global healthcare problem and the importance of hospital surfaces as a source of microbial contamination has been long been recognised. It is also of global concern that the prevention and treatment of HAIs is complicated by the pathogens frequently causing these HAIs are resistant to a wide range of antimicrobials and disinfectants. Good sanitation practices can limit and control microbial contamination, however, decontamination of hospital surfaces traditional cleaning methods is short term in nature; it is not long before contamination occurs again. This had led to the development of new approaches to solve this issue, Recently, innovative detergents containing non-pathogenic (not disease causing) probiotics (Probiotic Cleaning Hygiene System, PCHS) were shown to reduce the number of pathogens by 70-90% more than conventional disinfectants in several hospitals. This is due to them being able to compete with replace the disease causing pathogens due to a principle called competitive antagonism. They also reduced the number of drug-resistance genes present in the pathogens, leading to a drop in the number of the drug resistant pathogens themselves. Furthermore, the Bacillus species contained in the detergents (the probiotics) are genetically stable even after four years of continuous use and contact with surface pathogens, which means that they are safe to use for sanitizing purposes. Based on these observations, this study is looking at how a PCHS probiotic-based sanitizing intervention (treatment) may affect the number of how many HAIs rates when used in hospitals.

Who can participate?
People (of any age and either gender) that are patients of any hospitals taking part in the study.

What does the study involve?
The study has two phases. In the first phase, all hospitals continue with their usual sanitization procedures while initial (baseline) data is collected. This includes data on the number of HAIs, number of HAIs caused by drug resistant pathogens, type of HAIs present and degree of hospital surface contamination. In the second phase, the PCHS probiotic-based sanitizing intervention is

introduced in six out of the seven hospitals. One hospital is not given access to the PCHS probiotic-based sanitizing intervention and acts as the control for the study. The remaining six hospitals are split into two groups and are given access to the PCHS probiotic-based sanitizing intervention at different time, with a 6 month wait between, in order to minimize variations according to seasonal variations. There are no other changes made to factors known to affect the rate of HAIs , for example, standard precautions, hand hygiene, staff education and accountability, facilities and dedicated resources available for HAI surveillance. The same data gathered at the start of the study is collected again from each of the hospitals 6 months into the study and at 15 months.

What are the possible benefits and risks of participating?
All the patients participating to the study will not be treated any differently to normal at any point in the study, consequently, there are no risks for those taking part. Potential benefits are indirect, and are linked to a reduction of HAIs following the introduction of the probiotic-based cleaning strategy.

Where is the study run from?
Seven different hospitals in Italy.

When is the study starting and how long is it expected to run for?
October 2015 to July 2017

Who is funding the study?
COPMA scrl (Italy)

Who is the main contact?
1. Professor Sante Mazzacane (public)
2. Dr Elisabetta Caselli (scientific)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIAS-01

Study information

Scientific Title
Assessment of the effectiveness and safety of a probiotic-based sanitizing in limiting the number of healthcare associated infections: a multicenter, prospective, pre-post interventional study

Acronym
SAN-ICA

Study objectives
This study aims to assess the effectiveness of a PCHS (Probiotic Cleaning Hygiene System), a probiotic-based sanitizing method, in reducing the number of healthcare associated infections (HAIs) in hospital environments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. C Feltre ethics committee, 05/11/2015, ref: 841
2. Policlinico Universitario Gemelli, Romaethics committee, 15/10/2015, ref: 7243/15
3. Ospedali Riuniti di Foggia ethics committee, 13/07/2015, ref: 75/2015
4. Pavia ethics committee, 14/03/2016

5. Azienda Ospedaliero-Universitaria of Messina ethics committee protocol, 22/03/2016, ref: 2/16
6. Tolmezzo ethics committee - approval pending as of 13/06/2016

Study design
Multicenter pre-post interventional study

Primary study design
Interventional

Secondary study design

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Healthcare associated infections.

Interventions
The intervention will consist in the introduction of a new environmental probiotic-based sanitizing method (Probiotic Cleaning Hygiene System, PCHS), which will replace the traditional chemicals-based one. The procedure is based on the use of eco-sustainable detergents additioned with spores of apathogenic Bacillus strains, which have been shown capable of replacing pathogens on the treated surfaces, decreasing >90% their number and limiting the presence of drug-resistant species compared to conventional cleaning procedures. Cleaning staff will be adequately trained for the correct application of the PCHS system in all the seven hospitals participating to the study.

The study will be divided in two phases:
1. In the first phase of data collection (pre-intervention, 6 months) hospital settings will maintain traditional sanitizing procedures, based on chemical detergents/disinfectants (chlorine products)
2. At the end of the first phase the intervention will consist in the introduction of the PCHS system, which will take a period of 2/3 months needed for the stabilization of the system, afterwards a second phase (post-intervention, 6 months) of data collection will be performed

No changes will be applied to other parameters known to affect HAIs incidence, such as implementing standard precautions, particularly best hand hygiene practices at the bedside, improving staff education and accountability, improving facilities and dedicated resources available for HAI surveillance.
The seven hospital participating to the study will be divided in two groups, enrolled at different times (with a 6 months interval between the first and the second group), in order to minimize variations due to seasonal differences. In six out of seven hospitals, the data recorded in the post-intervention phase of the study will be directly compared with data recorded in pre-intervention phase (controls). One out of seven hospitals will not be subjected to the intervention (no treatment), for all the duration of the study (external control, observational study).

During the entire period of the study, specifically trained healthcare personnel will record continuously all HAI events developed in the hospital wards enrolled in the study. Each HAI will be characterized accordingly to CDC definition and parameters. Furthermore, a quote corresponding to at least 10 recorded HAIs per hospital setting will be validated by another hospital enrolled in the study, to minimize the risk of infection overcoding.

In parallel, the environmental contamination will be analyzed and characterized monthly in all the seven hospitals enrolled in the study, using both conventional and molecular methods, to collect data useful for correlating surface biodurden with HAIs incidence.

Intervention Type
Other

Primary outcome measure
1. Number of total healthcare associated infections (HAIs), recorded daily in all the hospitals enrolled in the study, before and after the application of PCHS, measured as number of HAI medical records collected at the end of the pre- and post-intervention phases, corresponding respectively to 6 and 15 months starting from the beginning of the study for each hospital setting
2. Surface bioburden quantitation and characterization in the pre- and post-intervention phases, in all the hospitals enrolled in the study, measured monthly by both conventional microbiological (pathogen quantitation) and molecular (pathogen characterization) analyses during all the study period

Secondary outcome measures
1. Number of HAIs sustained by multidrug resistant (MDR) microbial strains in the pre- and post-intervention phases in all the hospitals enrolled in the study, measured at the end of each phase, namely at 6 and 15 months starting from the beginning of the study for each hospital setting
2. Characterization of the HAIs typology, measuring the number of HAIs transmitted by contact with contaminated surfaces at the end of the pre- and post-intervention phases in all the hospitals enrolled in the study
3. Identification of a parameter correlating bioburden level/type with HAIs number

Overall study start date
01/10/2015

Completion date
30/07/2017

Eligibility

Key inclusion criteria
All the patients admitted to the wards of the seven hospital settings included in the study will be enrolled in the survey, without distinction of age or gender.

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
The study will recruit at least 100 beds/hospital, with a total number of 18,000 patients (about 9,000 in the pre-intervention phase and 9,000 in the post-intervention phase).

Key exclusion criteria
Participants that do not fulfill the inclusion criteria

Date of first enrolment
01/01/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Italy

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Sponsor type
Research organisation

Funder(s)

Funder type
Industry

Funder Name
COPMA scrl (Italy)

Results and Publications

Publication and dissemination plan
At the end of the study, we plan to publish the collected results. The publication date is expected within the end of 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/07/2018		Yes	No
Results article		27/02/2019	10/07/2023	Yes	No