Cluster Randomized Study Design Example (With Results)

Disclaimer: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

ClinicalTrials.gov Identifier: NCT00055633

Recruitment Status: Completed
First Posted: January 31, 2016
Results First Posted: February 28, 2019
Last Update Posted: February 28, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

This is a pragmatic, three-group, cluster randomized trial designed to compare strategies for preventing Poissonosis davrilarum (PD) infections in adult intensive care units (ICUs). ICUs will be assigned to one of three intervention strategies: standard care, targeted decolonization, or enhanced room disinfection. After a 12-month baseline period, ICUs will implement the assigned strategy for a 12-month intervention period.

Condition or disease	Intervention/treatment	Phase
Poissonosis Davrilarum Infection	Drug: 2% mupirocin cream Drug: 4% hydrogen peroxide sanitizing cloth Diagnostic Test: PD screening Other: Transmission-based precautions Other: Room disinfection	Phase 4

Detailed Description:

This is a three-group, cluster randomized trial designed to compare strategies for preventing PD infections in adult ICUs. ICUs will be assigned to one of the following three intervention strategies:

1. Standard care: consists of screening for PD on ICU admission and following transmission-based precaution policies, based on guidance from the Centers for Disease Control and Prevention
2. Targeted decolonization: includes screening for PD and following transmission-based precautions, as in Group 1. In addition, PD-positive patients will receive a 5-day decolonization regimen of twice-daily intranasal 2% No-Bug (mupirocin) cream and daily bathing with 4% No-Scrub (hydrogen peroxide) sanitizing cloths.
3. Enhanced room disinfection: includes screening for PD and following transmission-based precautions, as in Groups 1 and 2. In addition, rooms from which PD patients are discharged will be disinfected with a solution containing hypochlorite (bleach) plus a disinfecting ultraviolet light (UV-C) device.

The ICUs will be followed for 12 months during both the baseline and intervention periods.

Study Design

Study Type:	Interventional
Actual Enrollment:	236931 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	A Phase 4, Cluster Randomized Trial Comparing Two Interventions with Standard Practice to Reduce Poissonosis Davrilarum Infection in Intensive Care Units
Actual Study Start Date:	January 31, 2016
Actual Primary Completion Date:	January 30, 2018
Actual Study Completion Date:	January 30, 2018

Arms and Interventions

Arm	Intervention/treatment
Active Comparator: Group 1: Standard Care Patients were screened for Poissonosis davrilarum (PD) infection on intensive care unit (ICU) admission. Each enrolled ICU took transmission-based precautions, based on guidance from the Centers for Disease Control and Prevention (CDC).	Diagnostic Test: PD screening Patients were screened for PD infection on ICU admission. Other: Transmission-based precautions Transmission-based precautions (for example, ensuring appropriate use of personal protective equipment and limiting transport of patients) were based on guidance from the CDC.
Experimental: Group 2: Targeted Decolonization Plus Standard Care As in Group 1, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, PD-positive patients received a 5-day decolonization regimen of twice-daily intranasal 2% No-Bug cream (mupirocin) and daily bathing with 4% No-Scrub (hydrogen peroxide) sanitizing cloths.	Drug: 2% mupirocin cream Applied topically to infected area twice daily Other Name: 2% No-Bug cream Drug: 4% hydrogen peroxide sanitizing cloth Used for daily bathing across entire body Other Name: 4% No-Scrub sanitizing cloth Diagnostic Test: PD screening Patients were screened for PD infection on ICU admission. Other: Transmission-based precautions

Arm	Intervention/treatment
	Transmission-based precautions (for example, ensuring appropriate use of personal protective equipment and limiting transport of patients) were based on guidance from the CDC.
Experimental: Group 3: Enhanced Room Disinfection Plus Standard Care As in Groups 1 and 2, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, rooms from which PD patients were discharged were disinfected with a solution containing hypochlorite (bleach) plus a disinfecting ultraviolet light (UV-C) device.	Diagnostic Test: PD screening Patients were screened for PD infection on ICU admission. Other: Transmission-based precautions Transmission-based precautions (for example, ensuring appropriate use of personal protective equipment and limiting transport of patients) were based on guidance from the CDC. Other: Room disinfection Rooms were disinfected with a hypochlorite (bleach) solution plus a disinfection ultraviolet light (UV-C) device.

Outcome Measures

Primary Outcome Measures:

1. Incidence of Confirmed ICU-Attributable PD Infection [Time Frame: Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods, a total of 123,272 days for Group 1, 119,872 days for Group 2, and 136,922 days for Group 3]

   Intensive care unit (ICU)-attributable Poissonosis davrilarum (PD) infection is defined as a clinical culture that tests positive at any point from the third day after ICU admission through two days after discharge. Confirmed infections included any positive cultures collected from skin or mucosal surfaces and polymerase chain reaction (PCR)-verified bloodstream infections (BSIs).

2. Number of Confirmed ICU-Attributable PD Infections [Time Frame: Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods]

   ICU-attributable PD infection is defined as a clinical culture that tests positive at any point from the third day after ICU admission through two days after discharge. Confirmed infections included any positive cultures collected from skin or mucosal surfaces and PCR-verified BSIs.

Secondary Outcome Measures:

1. Incidence of BSI With Any Pathogen [Time Frame: Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods, a total of 123,272 days for Group 1, 119,872 days for Group 2, and 136,922 days for Group 3]

   BSI is based on the first eligible infection by any pathogen per patient. If a patient had more than one ICU-associated infection, the patient was counted only once. Pathogens were any gram-positive organism, gram-negative organism, PD, or Candida species confirmed by a laboratory culture.

2. Number of BSIs With Any Pathogen [Time Frame: Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods]

   BSI is based on the first eligible infection from any pathogen per patient. If a patient had more than one ICU-associated infection, the patient was counted only once. Pathogens were any gram-positive organism, gram-negative organism, PD, or Candida species confirmed by a laboratory culture.

3. Incidence of BSI With PD Associated With Central Line [Time Frame: Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods, a total of 123,272 days for Group 1, 119,872 days for Group 2, and 136,922 days for Group 3]

   PD central line-associated BSI (PD CLABSI) was a primary BSI in a patient who had a central line within the 48-hour period before the development of the BSI.

4. Number of BSIs with PD Associated With Central Line [Time Frame: Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods]

   PD CLABSI was a primary BSI in a patient who had a central line within the 48-hour period before the development of the BSI.

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Commitment by the hospital's administration to have all its intensive care units (ICUs) randomized for the trial
- Less than 30% of patients in participating adult ICUs currently receiving either 4% No-Scrub sanitizing cloths or intranasal 2% No-Bug cream at baseline
- Stable use of infection-prevention initiatives and products during the baseline period

Exclusion Criteria:

- Adoption of new infection-control initiatives that would conflict with the study protocol

Contacts and Locations

Locations

United States, Tennessee

Southern Innovative Clinical Health System (SICHS)

Nashville, Tennessee, United States, 37218

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] January 1, 2016

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055633
Other Study ID Numbers:	TTTClusterRandomizedR
First Posted:	January 31, 2016
Results First Posted:	February 28, 2019
Last Update Posted:	February 28, 2019

Last Verified: January 2019

Human Subjects Protection Review Board Status: Approved
Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No

Study Results

Participant Flow

Recruitment Details	201 ICUs in 140 SICHS hospitals were screened.
Pre-assignment Details	78 ICUs in 45 hospitals were randomized; 4 were excluded before the baseline period (met the exclusion criterion). All ICUs in a hospital and all adults in those ICUs were assigned to the same group. Participants were counted only once during the study (first ICU visit) and did not overlap in the baseline and intervention periods.

Arm/Group Title	Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▼ Arm/Group Description	Patients were screened for Poissonosis davrilarum (PD) infection on intensive care unit (ICU) admission. Each enrolled ICU took transmission-based precautions, based on guidance from the Centers for Disease Control and Prevention (CDC).	As in Group 1, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, PD-positive patients received a 5-day decolonization regimen of twice-daily intranasal 2% No-Bug cream and daily	As in Groups 1 and 2, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, rooms from which PD patients were discharged were disinfected with a solution containing hypochlorite

		bathing with 4% No-Scrub sanitizing cloths.		(bleach) plus a disinfecting ultraviolet light (UV-C) device.	
Period Title: **Baseline Period: Months 1-12**						
Type Units Assigned: Intensive Care Units	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)
Started	39530	23	41229	22	38804	29
Completed	39530	23	41229	22	38804	29
Not Completed	0	0	0	0	0	0
Period Title: **Intervention Period: Months 13-24**						
Type Units Assigned: Intensive Care Units	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)
Started	39123	23	41103	22	38789	29
Completed	39123	23	39456	20	38789	29
Not Completed	0	0	1647	2	0	0
Reason Not Completed						
Withdrawal of ICUs	0		1647		0	

Baseline Characteristics

Arm/Group Title		Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care	Total
▶ Arm/Group Description		Patients were screened for Poissono…	As in Group 1, patients were screen…	As in Groups 1 and 2, patients were…	Total of all reporting groups
Overall Number of Baseline Participants		78653	80685	77593	236931
Overall Number of Units Analyzed Type of Units Analyzed: Intensive Care Units		23	22	29	74
▼ Baseline Analysis Population Description		[Not Specified]			
Age, Continuous [1] Median (Inter-Quartile Range) Unit of measure: years					
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants	119563 participants
		63 (51 to 76)	66 (54 to 78)	67 (55 to 79)	65 (52 to 77)
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants	117368 participants
		64 (52 to 77)	65 (53 to 77)	66 (54 to 78)	65 (52 to 77)

		[1] Measure Analysis Population Description: Participants assessed for age in the baseline and intervention periods			
Sex: Female, Male [1] Measure Type: Count of Participants Unit of measure: Participants					
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants	119563 participants
	Female	19014 48.1%	20367 49.4%	20100 51.8%	59481 49.7%
	Male	20516 51.9%	20862 50.6%	18704 48.2%	60082 50.3%
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants	117368 participants
	Female	18427 47.1%	19412 49.2%	18929 48.8%	56768 48.4%
	Male	20696 52.9%	20044 50.8%	19860 51.2%	60600 51.6%
		[1] Measure Analysis Population Description: Participants assessed for sex in the baseline and intervention periods			
Ethnicity (NIH/OMB) [1] Measure Type: Count of Participants Unit of measure: Participants					
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants	119563 participants
	Hispanic or Latino	910 2.3%	985 2.4%	1501 3.9%	3396 2.8%

	Not Hispanic or Latino	38620 97.7%	40244 97.6%	37303 96.1%	116167 97.2%
	Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants	117368 participants
	Hispanic or Latino	896 2.3%	963 2.4%	1,479 3.8%	3,338 2.8%
	Not Hispanic or Latino	38227 97.7%	38493 97.6%	37310 96.2%	114030 97.2%
	Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%	0 0.0%
		[1] Measure Analysis Population Description: Participants assessed for ethnicity in the baseline and intervention periods			
Race (NIH/OMB) [1] Measure Type: Count of Participants Unit of measure: Participants					
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants	119563 participants
	American Indian or Alaska Native	420 1.1%	859 2.1%	560 1.4%	1839 1.5%

	Asian	1962 5.0%	1209 2.9%	2737 7.1%	5908 4.9%
	Native Hawaiian or Other Pacific Islander	131 0.3%	244 0.6%	169 0.4%	544 0.5%
	Black or African American	8386 21.2%	9882 24.0%	9821 25.3%	28089 23.5%
	White	28631 72.4%	29035 70.4%	25517 65.8%	83183 69.6%
	More than one race	0 0.0%	0 0.0%	0 0.0%	0 0.0%
	Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants	117368 participants
	American Indian or Alaska Native	391 1.0%	659 1.7%	581 1.5%	1631 1.4%
	Asian	1956 5.0%	1009 2.6%	2715 7.0%	5680 4.8%
	Native Hawaiian or Other Pacific Islander	129 0.3%	158 0.4%	171 0.4%	458 0.4%

	Black or African American	8215 21.0%	9182 23.3%	9697 25.0%	27094 23.1%
	White	28432 72.7%	28448 72.1%	25625 66.1%	82505 70.3%
	More than one race	0 0.0%	0 0.0%	0 0.0%	0 0.0%
	Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%	0 0.0%
		[1] Measure Analysis Population Description: Participants assessed for race in the baseline and intervention periods			
Region of Enrollment (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants					
United States	Number Analyzed	78653 participants	80685 participants	77593 participants	236931 participants
		78653 100.0%	80685 100.0%	77593 100.0%	236931 100.0%
Intensive Care Unit Type [1] Measure Type: Count of Units Unit of measure:					

Intensive Care Units					
Baseline Period	Number Analyzed	23 Intensive Care Units [2]	22 Intensive Care Units [3]	29 Intensive Care Units [4]	74 Intensive Care Units [5]
	Medical Only	3 13.0%	3 13.6%	2 6.9%	8 10.8%
	Surgical Only	2 8.7%	4 18.2%	3 10.3%	9 12.2%
	Medical and Surgical	18 78.3%	15 68.2%	24 82.8%	57 77.0%
Intervention Period	Number Analyzed	23 Intensive Care Units [6]	20 Intensive Care Units [7]	29 Intensive Care Units [8]	72 Intensive Care Units [9]
	Medical Only	3 13.0%	1 5.0%	2 6.9%	6 8.3%
	Surgical Only	2 8.7%	4 20.0%	3 10.3%	9 12.5%
	Medical and Surgical	18 78.3%	15 75.0%	24 82.8%	57 79.2%

[1] Measure Analysis Population Description: Data not available for the two ICUs in Group 2 that withdrew during the intervention period

[2] 39530 participants

[3] 41229 participants

[4] 38804 participants

[5] 119563 participants

[6] 39123 participants

[7] 39456 participants

[8] 38789 participants

[9] 117368 participants

Number of Participants With Prior PD Infection [1] [2] Measure Type: Count of Participants Unit of measure: Participants					
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants	119563 participants
		3826 9.7%	4025 9.8%	3911 10.1%	11762 9.8%
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants	117368 participants
		4951 12.7%	4783 12.1%	4112 10.6%	13846 11.8%
		[1] Measure Description: Prior infections were those that occurred 1 year prior to admission through day 2 of the ICU stay for the baseline or intervention period. [2] Measure Analysis Population Description: Participants assessed for prior PD infection in the baseline and intervention periods			

Outcome Measures

1. Primary Outcome

Title	Incidence of Confirmed ICU-Attributable PD Infection
▼ Description	Intensive care unit (ICU)-attributable Poissonosis davrilarum (PD) infection is defined as a clinical culture that tests positive at any point from the third day after ICU admission through two days after discharge. Confirmed infections included any positive cultures collected from skin or mucosal surfaces and polymerase chain reaction (PCR)-verified bloodstream infections (BSIs).

Time Frame	Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods, a total of 123,272 days for Group 1, 119,872 days for Group 2, and 136,922 days for Group 3

▼Outcome Measure Data

▼ Analysis Population Description

Participants assessed for ICU-attributable PD-positive culture in the baseline and intervention periods

Arm/Group Title		Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▶ Arm/Group Description:		Patients were screened for Poissono…	As in Group 1, patients were screen...	As in Groups 1 and 2, patients were...
Overall Number of Participants Analyzed		78653	80685	77593
Measure Type: Number Unit of Measure: Infections per 1,000 Patient-Days				
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants
		3.3	4.1	3.5
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants
		3.0	3.2	2.2

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care, Group 2: Targeted Decolonization Plus Standard Care, Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	Test of all three intervention groups being equal
	Type of Statistical Test	Superiority

	Comments	We powered the study using the rarest outcome (PD BSI associated with central line) and designed the study to have 80% power to detect a moderate effect, i.e., a 40% reduction in the rate of PD infection in Group 2 and a 60% reduction in Group 3, compared with Group 1.
Statistical Test of Hypothesis	P-Value	0.01
	Comments	The threshold for significance was set at p < 0.05. It was prespecified that if the difference in hazard ratios across groups was significant, pairwise comparisons would be performed as a follow-up analysis.
	Method	Regression, Cox
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Intracluster Correlation Coefficient]
	Estimated Value	0.298
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care, Group 2: Targeted Decolonization Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.09
	Comments	The threshold for significance was set at p < 0.05.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care, Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.003
	Comments	The threshold for significance was set at p < 0.05.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Group 2: Targeted Decolonization Plus Standard Care, Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.16
	Comments	The threshold for significance was set at p < 0.05.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 5

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
	Estimation Parameter	Hazard Ratio (HR)

Method of Estimation	Estimated Value	0.92
	Confidence Interval	(2-Sided) 95% 0.77 to 1.10
	Estimation Comments	Hazard ratios for all outcomes were calculated using a Cox Proportional Hazard model and reflect a comparison of the incidence rates between the baseline and intervention periods.

▼ Statistical Analysis 6

Statistical Analysis Overview	Comparison Group Selection	Group 2: Targeted Decolonization Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.77
	Confidence Interval	(2-Sided) 95% 0.64 to 0.92
	Estimation Comments	Calculated using Cox Proportional Hazard model

▼ Statistical Analysis 7

Statistical Analysis Overview	Comparison Group Selection	Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.63
	Confidence Interval	(2-Sided) 95% 0.53 to 0.74

	Estimation Comments	Calculated using Cox Proportional Hazard model

2. Primary Outcome

Title	Number of Confirmed ICU-Attributable PD Infections
▼ Description	ICU-attributable PD infection is defined as a clinical culture that tests positive at any point from the third day after ICU admission through two days after discharge. Confirmed infections included any positive cultures collected from skin or mucosal surfaces and PCR-verified BSIs.
Time Frame	Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods

▼ Outcome Measure Data

▼ Analysis Population Description

Participants assessed for ICU-attributable PD infections in the baseline and intervention periods

Arm/Group Title		Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▶ Arm/Group Description:		Patients were screened for Poissono...	As in Group 1, patients were screen...	As in Groups 1 and 2, patients were...
Overall Number of Participants Analyzed		78653	80685	77593
Measure Type: Number Unit of Measure: PD Infections				
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants
		215	240	249
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants
		178	199	143

3. Secondary Outcome

Title	Incidence of BSI With Any Pathogen
▼ Description	BSI is based on the first eligible infection by any pathogen per patient. If a patient had more than one ICU-associated infection, the patient was counted only once. Pathogens were any gram-positive organism, gram-negative organism, PD, or Candida species confirmed by a laboratory culture.
Time Frame	Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods, a total of 123,272 days for Group 1, 119,872 days for Group 2, and 136,922 days for Group 3

▼ Outcome Measure Data

▼ Analysis Population Description
Participants assessed for BSI with any pathogen in the baseline and intervention periods

Arm/Group Title		Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▶ Arm/Group Description:		Patients were screened for Poissono...	As in Group 1, patients were screen...	As in Groups 1 and 2, patients were...
Overall Number of Participants Analyzed		78653	80685	77593
Measure Type: Number Unit of Measure: Infections per 1,000 Patient-Days				
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants
		3.9	4.8	6.1
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants
		3.8	3.7	3.3

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care, Group 2: Targeted Decolonization Plus Standard Care, Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	Test of all three intervention groups being equal
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	< 0.001
	Comments	The threshold for significance was set at p < 0.05. It was prespecified that if the difference in hazard ratios across groups was significant, pairwise comparisons would be performed as a follow-up analysis.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care, Group 2: Targeted Decolonization Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.05
	Comments	The threshold for significance was set at p < 0.05.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care, Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	[Not specified]

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	< 0.001
	Comments	The threshold for significance was set at p < 0.05.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Group 2: Targeted Decolonization Plus Standard Care, Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.04
	Comments	The threshold for significance was set at p < 0.05.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 5

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.97
	Confidence Interval	(2-Sided) 95% 0.83 to 1.14

	Estimation Comments	Calculated using Cox Proportional Hazard model

▼ Statistical Analysis 6

Statistical Analysis Overview	Comparison Group Selection	Group 2: Targeted Decolonization Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.77
	Confidence Interval	(2-Sided) 95% 0.65 to 0.90
	Estimation Comments	Calculated using Cox Proportional Hazard model

▼ Statistical Analysis 7

Statistical Analysis Overview	Comparison Group Selection	Group 3: Enhanced Room Disinfection + Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.55
	Confidence Interval	(2-Sided) 95% 0.48 to 0.62
	Estimation Comments	Calculated using Cox Proportional Hazard model

4. Secondary Outcome

Title	Number of BSIs With Any Pathogen
▼ Description	BSI is based on the first eligible infection from any pathogen per patient. If a patient had more than one ICU-associated infection, the patient was counted only once. Pathogens were any gram-positive organism, gram-negative organism, PD, or Candida species confirmed by a laboratory culture.
Time Frame	Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods

▼ Outcome Measure Data

▼ Analysis Population Description
Participants assessed for BSIs with any pathogen in the baseline and intervention periods

Arm/Group Title		Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▶ Arm/Group Description:		Patients were screened for Poissono...	As in Group 1, patients were screen...	As in Groups 1 and 2, patients were...
Overall Number of Participants Analyzed		78653	80685	77593
Measure Type: Number Unit of Measure: BSIs				
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants
		251	269	413
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants
		225	229	220

5. Secondary Outcome

Title	Incidence of BSI with PD Associated With Central Line
▼ Description	PD central line-associated BSI (PD CLABSI) was a primary BSI in a patient who had a central line within the 48-hour period before the development of the BSI.
Time Frame	Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods, a total of 123,272 days for Group 1, 119,872 days for Group 2, and 136,922 days for Group 3

▼ Outcome Measure Data

▼ Analysis Population Description
Participants assessed for PD CLABSI in the baseline and intervention periods

Arm/Group Title		Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▶ Arm/Group Description:		Patients were screened for Poissono...	As in Group 1, patients were screen...	As in Groups 1 and 2, patients were...
Overall Number of Participants Analyzed		78653	80685	77593
Measure Type: Number Unit of Measure: Infections per 1,000 Patient-Days				
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants
		0.7	0.8	1.4
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants
		0.9	1.0	0.9

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care, Group 2: Targeted Decolonization Plus Standard Care, Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	Test of all three intervention groups being equal
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.08
	Comments	The threshold for significance was set at $p < 0.05$. It was prespecified that if the difference in hazard ratios across groups was significant, pairwise comparisons would be performed as a follow-up analysis.
	Method	Regression, Cox
	Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Group 1: Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	1.22
	Confidence Interval	(2-Sided) 95% 0.80 to 1.79
	Estimation Comments	Calculated using Cox Proportional Hazard model

▼ Statistical Analysis 3

	Comparison Group Selection	Group 2: Targeted Decolonization Plus Standard Care

Statistical Analysis Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	1.20
	Confidence Interval	(2-Sided) 95% 0.81 to 2.01
	Estimation Comments	Calculated using Cox Proportional Hazard model

▼ Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Group 3: Enhanced Room Disinfection Plus Standard Care
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.70
	Confidence Interval	(2-Sided) 95% 0.47 to 1.02
	Estimation Comments	Calculated using Cox Proportional Hazard model

6. Secondary Outcome

Title	Number of BSIs With PD Associated With Central Line
▼ Description	PD CLABSI was a primary BSI in a patient who had a central line within the 48-hour period before the development of the BSI.
Time Frame	Assessed from 3 days after ICU admission to 2 days post discharge for each participant during the baseline (12 months) and intervention (12 months) periods

▼ Outcome Measure Data

▼ Analysis Population Description

Participants assessed for PD CLABSIs in the baseline and intervention periods

Arm/Group Title		Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▶ Arm/Group Description:		Patients were screened for Poissono...	As in Group 1, patients were screen...	As in Groups 1 and 2, patients were...
Overall Number of Participants Analyzed		78653	80685	77593
Measure Type: Number Unit of Measure: PD BSIs				
Baseline Period	Number Analyzed	39530 participants	41229 participants	38804 participants
		45	47	101
Intervention Period	Number Analyzed	39123 participants	39456 participants	38789 participants
		55	61	60

Adverse Events

Time Frame	Serious adverse events (SAEs): from intensive care unit (ICU) intake through 2 days after ICU discharge during the intervention period; Other (Not Including Serious) Adverse Events (OAEs): from 3 days after ICU intake through 2 days after ICU discharge
Adverse Event Reporting Description	Data on anticipated SAEs (sepsis, anaphylaxis, and bloodstream infection (BSI)-attributable deaths) were collected for all arms. All deaths were the result of BSIs. Only anticipated OAEs (intranasal rash and pruritis) that may have been attributed to intranasal 2% No-Bug cream or 4% No-Scrub

	sanitizing cloths were collected; participants in Groups 1 and 3 were not assessed for OAEs.
Source Vocabulary Name for Table Default	[Not specified]
Collection Approach for Table Default	Systematic Assessment

Arm/Group Title	Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care
▶ Arm/Group Description	Patients were screened for Poissono...	As in Group 1, patients were screen...	As in Groups 1 and 2, patients were...

All-Cause Mortality

	Group 1: Standard Care	**Group 2: Targeted Decolonization Plus Standard Care**	**Group 3: Enhanced Room Disinfection Plus Standard Care**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	27/39123 (0.07%)	28/39456 (0.07%)	26/38789 (0.07%)

▼ **Serious Adverse Events**

	Group 1: Standard Care	**Group 2: Targeted Decolonization Plus Standard Care**	**Group 3: Enhanced Room Disinfection Plus Standard Care**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	182/39123 (0.47%)	187/39456 (0.47%)	186/38789 (0.48%)
General disorders			
Anaphylaxis †	2/39123 (0.01%)	0/39456 (0%)	3/38789 (0.01%)
Infections and infestations			
Sepsis †	180/39123 (0.46%)	187/39456 (0.47%)	183/38789 (0.47%)

† Indicates events were collected by systematic assessment

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%		
	Group 1: Standard Care	**Group 2: Targeted Decolonization Plus Standard Care**	**Group 3: Enhanced Room Disinfection Plus Standard Care**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/0	22/39456 (0.06%)	0/0
Skin and subcutaneous tissue disorders			
Intranasal rash †	0/0	7/39456 (0.02%)	0/0
Pruritus †	0/0	15/39456 (0.04%)	0/0

† Indicates events were collected by systematic assessment

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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Responsible Party: PRS Results Training
ClinicalTrials.gov Identifier: NCT00055633
Other Study ID Numbers: TTTClusterRandomizedR
First Submitted: January 26, 2016

First Posted:	January 31, 2016
Results First Submitted:	January 30, 2019
Results First Posted:	February 28, 2019
Last Update Posted:	February 28, 2019