

ORAL PRESENTATION

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# Randomized, placebo-controlled, double-blind clinical trial to evaluate the efficacy of polyhexanide for topical decolonization of methicillin-resistant *Staphylococcus aureus* (MRSA) carriers

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From 3rd International Conference on Prevention and Infection Control (ICPIC 2015) Geneva, Switzerland. 16-19 June 2015

## Introduction

Due to increasing resistance, alternatives to mupirocin and chlorhexidine for decolonization of MRSA carriage need to be evaluated.

## Objectives

To evaluate the efficacy of polyhexanide (Prontoderm<sup>®</sup>) vs placebo in eliminating MRSA carriage at day 28 (D28) after the end of treatment.

## Methods

In a 1,900-bed teaching hospital, MRSA-colonized patients were randomized into a double-blind, placebo-controlled superiority trial. Patients were treated with either polyhexanide (antiseptic and surface-active substances; group I) or placebo (only surface-active substances; group P) applied to the anterior nares and skin for 10 days. The primary outcome was MRSA decolonization at D28 assessed by both intention-to-treat ([ITT] responder analysis) and per-protocol (PP) analysis (microbiological follow-up  $\pm$  7 days and topical treatment  $\geq$  5 days). Secondary outcomes included MRSA decolonization according to nasal MRSA carriage, safety and emergence of resistance.

## Results

Of 2590 patients screened, 146 patients (group I, 71; group P, 75) were randomized between January 2011 and July 2014. Primary outcome was missing for 11 (7.5%) patients. ITT analysis showed that 24/71 (33.8%) patients in group I vs 22/75 (29.3%) in group P were MRSA-free at D28 (risk difference, 4.5%; 95% CI, -10.6% to 19.5%;  $P=0.56$ ). PP analysis confirmed the results with 19/53 (35.8%) decolonized polyhexanide-treated patients vs 17/56 (30.4%) in the placebo arm (risk difference, 5.5%; 95% CI, -12.2% to 23.0%;  $P=0.54$ ). In the subgroup of MRSA nasal carriers, PP analysis showed that 6/15 (40.0%) patients in group I vs 2/11 (18.2%) in group P were decolonized ( $P=0.40$ ). Nine serious adverse events occurred in group I vs 12 in group P; none was attributable to study medication. Emergence of polyhexanide resistance was not observed.

## Conclusion

This study suggests that under real-life conditions a single polyhexanide decolonization course is marginally effective in eradicating MRSA carriage.

## Disclosure of interest

C. Landelle: None declared, E. Von Dach: None declared, T. Hausteiner: None declared, A. Agostinho: None declared, G. Renzi: None declared, A. Renzoni: None declared, D. Pittet: None declared, J. Schrenzel: None declared, P. François: None declared, S. Harbarth

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Grant/Research support from: a peer-reviewed research grant funded by Pfizer, Consultant for: the advisory boards of Destiny Pharma, bioMerieux, Novartis, and DaVolterra

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Published: 16 June 2015

doi:10.1186/2047-2994-4-S1-O6

**Cite this article as:** Landelle *et al.*: Randomized, placebo-controlled, double-blind clinical trial to evaluate the efficacy of polyhexanide for topical decolonization of methicillin-resistant *Staphylococcus aureus* (MRSA) carriers. *Antimicrobial Resistance and Infection Control* 2015 **4**(Suppl 1):O6.

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