

ORAL PRESENTATION

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O057: Clinical evaluation of the antiseptic efficacy and local tolerability of a polihexanide-based antiseptic in comparison to a chlorhexidine-based antiseptic on intact skin

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Introduction

The antiseptic agent chlorhexidine is internationally widely-used and well-accepted for skin and wound antiseptics. In recent years, the agent polihexanide is gaining importance for similar purposes. Both agents are biguanides and therefore similar characteristics may be expected.

Objectives

The primary objective of this study was to compare the antimicrobial efficacy of polihexanide 0.02 % and 0.04 % with chlorhexidine 0.05 % after 30 min of treatment of healthy skin. The secondary objectives were to evaluate the local tolerability and the antimicrobial efficacy after 5 and 10 min contact time.

Methods

The study was performed as a double-blind, randomized, comparator-controlled, 3-arm, crossover study on 20 healthy volunteers with intact skin in a phase 1 study unit.

Test areas of 5 cm² on the subjects' arms were treated with investigational and reference products using a polyurethane swab. Skin swabs were taken before and after treatment for quantitative microbial evaluation.

The main outcome measure was the log₁₀ reduction factor (RF) of colony-forming units (cfu) on the skin after 30 minutes of treatment. Further endpoints were the RF after 5 and 10 minutes and the local tolerability.

Results

No statistically significant difference was seen between the test products polihexanide 0.02 %, 0.04 % and the comparator, chlorhexidine 0.05 % after 30 min of treatment ($p > 0.1$). The analysis of the exposure times of 5 and 10 minutes revealed that the antiseptic efficacy of polihexanide 0.02 % is statistically significantly lower than that for the comparator chlorhexidine; polihexanide 0.04 % on the contrary not. No statistically significant differences in local tolerability were observed between the three products [1].

Conclusion

The results of this clinical study indicate that polihexanide is a suitable alternative to chlorhexidine and shows a comparative efficacy on the skin.

Disclosure of interest

None declared.

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