Clinical Trial Synopsis

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Name of Sponsor/ Company: Dr. August Wolff GmbH & Co. KG Arzneimittel	Individual Study Table Referring to Part of the Dossier Volume: Page:	*(For National Authority Use only)*
Name of Finished Product: Octenidine 0.1 % Wound Gel		
Name of Active Ingredient: 0.1% octenidine dihydrochloride		
Title of study: Local antibacterial efficacy of a gel containing 0.1 % octenidine dihydrochloride on pre-damaged skin		
Identifiers: Sponsor study code: OCG-15/2010 EudraCT number: 2010-024572-25 NCT number: -		
Study centre(s): 1 recruiting site in Germany		
Publication (reference): -		
Study period: Date of first enrolment: May 23rd, 2011 Date of last completed: May 30th, 2011	**Phase of development:** Phase II	
Objective: Determination of the antibacterial efficacy (reduction of bacterial count) of the wound gel (IP) on previously damaged (tape stripped) skin in comparison to placebo and in comparison to initial bacterial count.		

Methodology:

Monocentric, randomized, placebo-controlled, double-blind, phase II study.

4 test areas were marked at each forearm (one area per arm served as control area for determination of initial bacterial count and as initial baseline value). Tape-stripping was performed at all 8 test areas. After stripping, each test area was incubated for 24 ± 2 hours with autologous blood in order to increase the bacterial load of the test areas and to imitate conditions of superficial wounds. After removal of the test chambers, sampling for determination of the initial bacterial load of the two control areas was performed. The other 6 test areas were treated for 1h, 3h and 6h either with the test product or with placebo. After each application period samples were taken.

Number of patients (planned and analysed)

Enrolled: 44

Analysed: 43 (ITT); 41 (PP)

Diagnosis and main criteria for inclusion:

Caucasian men and women (skin type I to IV, Fitzpatrick et al. 1974), age 18 to 70 with healthy skin at the test areas and an initial bacterial load at the test areas of at least $10^5/cm^2$.

Test product, dose and mode of administration, batch number:

Product: Octenidine 0.1 % Wound Gel

Mode of administration: Topical, three times for different periods (1h, 3h and 6h)

Batch number: 10590

Duration of treatment:

1h, 3h and 6h

Reference therapy, dose and mode of administration, batch number:

Matched placebo gel

Batch number: 10590

Criteria for evaluation:

Primary objective:

- The primary objective is a significant reduction of total bacterial count after 3h, 6h and 1h of application compared to placebo.

Secondary objectives:

- Significant reduction of total bacterial count after 1h, 3h and 6h of application compared to untreated.
- Safety parameters (including skin tolerability, assessment of burning/itching and erythema) are documented and analyzed

Statistical methods:

- T-test for paired data
- Hierarchical testing to adjust for multiplicity
- 95 % confidence intervals

Summary – Conclusions

Efficacy results:

After application of the wound gel (IP) bacteria counts at the respective areas were lower compared to bacteria counts of test areas treated with placebo. All three H0-hypothesis were rejected with one-sided type I error 0.025; with this efficacy of the wound gel (IP) was shown for all three application times.

Application of both treatments reduced bacteria counts compared to control area at all assessment time points. All limits of the 95 % confidence intervals showed values lower than "0".

Safety results:

Skin tolerability assessed by the occurrence of burning/stinging and erythema. Only a very few reactions, such as burning/stinging were assessed after application of the investigational product and the placebo. Erythema was observed once after 1h application of the wound gel (IP).

No adverse events were seen in this study.

There were no relevant changes in heart rate and blood pressure between screening and final visit. All female women of childbearing potential had a negative pregnancy test at screening.

Conclusions:

A significant reduction of bacterial counts after application of the wound gel (IP) was proven for all three application times in comparison to placebo. With this the primary objective of this study was proven. Application of the wound gel (IP) for 1, 3, and 6 hours resulted in a significant reduction of the bacterial load compared to untreated for all three different application periods. The placebo itself was also effective in reducing the bacterial load after all three application periods, indicating that the base of the investigational product had also a slight anti-bacterial effect. The tolerability of the wound gel (IP) and the placebo can be judged as very good since only a very few reactions such as burning/stinging and erythema were observed during the study. The observed development of erythema during the study course is most likely caused by the test procedure, i.e. tape stripping, incubation with autologous blood and occlusive application. No serious and no non-serious adverse events occurred in this study. There were no clinically relevant changes in blood pressure and heart rate in this study. The results of the safety parameters did not show any negative aspects regarding safety in this study.

Date of report: 10th of October 2011