Prontosan® Wound Irrigation Solution vs. saline

# Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic wounds: a single-blind RCT

Bellingeri A, Falciani F, Traspedini P, Moscatelli A, Russo A, Tino G, Chiari P, Peghetti A. Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic wounds: a single-blind RCT. J Wound Care. 2016 Mar;25(3):160, 162-6, 168. doi: 10.12968/jowc.2016.25.3.160. PMID: 26947697.

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## Study overview

### Comparator
Prontosan® Wound Irrigation Solution vs. saline

### Type of study
Clinical, single-blinded, multi-center, randomized controlled trial (RCT)

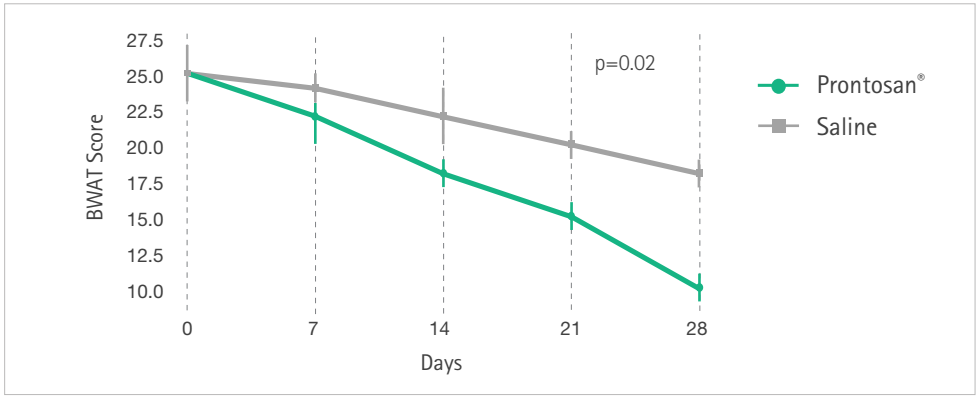
### Objective
To assess the efficacy of Prontosan® Solution in wound size reduction, inflammation management, and healing progression versus normal saline solution

### Patient population
289 patients with pressure ulcers (PUs) or venous leg ulcers from 6 centers across Italy

### Timeframe
Data collected over 28 days with assessments at five time points (Day 0, 7, 14, 21, 28)

## Main findings

### Faster & better healing
BWAT Score shows significant improvement: Bates-Jensen Wound Assessment Tool shows lower score (p=0.02) with Prontosan®, indicating faster and better healing.




### Wound size reduction
Prontosan® reduces wound size significantly in 28 days (p<0.05) vs. saline.

### Granulation tissue
Faster formation with Prontosan® (p=0.04) vs. saline.

### Inflammation control
- Prontosan® is more effective at controlling inflammation (p=0.03) compared to saline.
- Improved exudate type/amount, surrounding skin color, edema, and induration.

### Safety
No treatment-related adverse events observed.

## Clinical relevance*

### Effective wound healing
Patients treated with Prontosan® showed faster reductions in wound size and inflammation. The findings suggest that Prontosan® Solution could enhance wound healing outcomes compared to traditional saline.

### Reduction in inflammation
Significant reductions in inflammation highlight Prontosan®'s potential role in preventing chronic wounds from worsening due to infection or prolonged inflammation.

### Safe and tolerable
Prontosan® was shown to be safe for use, with no adverse events reported in the trial, and no increase in pain levels, making it a reliable option for regular use in chronic wound management.

*Reflects B. Braun's interpretation and not the original authors' conclusions.

# Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic wounds: a single-blind RCT

Prontosan® Wound Irrigation Solution vs. saline


## Summary

The study by Bellingeri *et al.* evaluated the efficacy of Prontosan® Solution in treating chronic wounds, such as PUs and venous leg ulcers, through a single-blind, multi-center randomized controlled trial. The study involved 289 patients from six centers across Italy, with data collected over 28 days.

Key findings include a significant reduction in wound size (p=0.04) and faster granulation tissue formation (p=0.04) in patients treated with Prontosan® compared to those treated with normal saline. Prontosan® was also more effective in controlling inflammation, as evidenced by improved Bates-Jensen Wound Assessment Tool (BWAT) scores (p=0.03). Additionally, the solution improved overall wound condition (p=0.02) without increasing patient discomfort, as no significant differences in pain levels were observed between groups.


**Prontosan® demonstrates significantly higher efficacy compared to saline in reducing inflammatory signs and accelerating the healing of vascular leg ulcers and pressure ulcers, supporting the revision and update of chronic wound care protocols.**

## Study at a glance *(Bellingeri et al. J Wound Care; 2016)*

### Objective
To assess the efficacy of Prontosan® Solution in wound size reduction, inflammation management, and healing progression.

### Type of study
Clinical, single-blind, multi-center, randomized controlled trial (RCT).

### Patient population
289 patients with PUs or vascular leg ulcers from 6 centers across Italy.

### Timeframe
Data collected over 28 days, with assessments at five time points (Day 0, 7, 14, 21, 28).

## Main findings

### Versus normal saline solution (at study end)

- The total BWAT score significantly improved (p=0.02), showing faster and more effective wound healing.
- Significant reduction in wound size over 28 days ($p<0.05$).
- Faster granulation tissue formation (p=0.04).
- Improvement in Bates-Jensen Wound Assessment Tool (BWAT) inflammatory score (p=0.03).
- Better results in reducing key inflammation indicators (exudate type/amount, surrounding skin color, peripheral tissue edema, and induration).
- No significant difference in pain levels.
- No adverse events.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