COMPARISON OF EscharEx®, BROMELAIN-BASED ENZYMATIC DEBRIDEMENT, TO COLLAGENASE SANTYL® OINTMENT - ANALYSES FROM THE CHRONEX MULTICENTER RCT

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Overview

INTRODUCTION

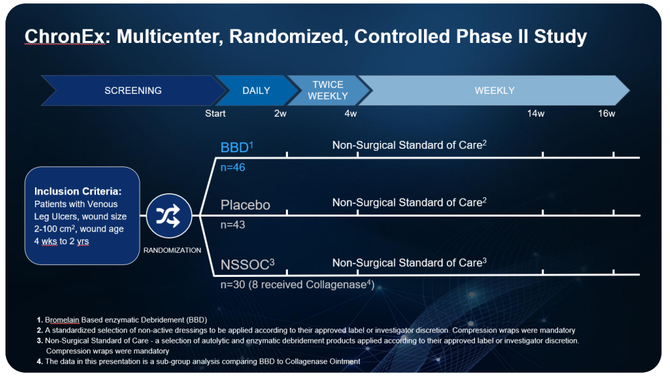
Results from the ChronEx Phase II RCT assessing a novel bromelain-based enzymatic debridement drug (BBD, EscahrEx®) in the treatment of chronic venous leg ulcers (VLU) were published previously. BBD was superior to hydrogel placebo and non-surgical standard of care (NSSOC), in complete debridement and complete granulation, key components of wound bed preparation (WBP). One of the NSSOC used in the study was collagenase SANTYL® Ointment, approved in the US for debridement of chronic dermal ulcers.
Post-hoc analyses assess the efficacy of BBD vs. Collagenase in VLU in the ChronEx study.

METHODS

In ChronEx, patients with chronic VLU were randomized (3:3:2 ratio) to daily treatment with BBD, placebo, or NSSOC, for up to 2 weeks or until reaching complete debridement, whichever occurred first, and then managed weekly with NSSOC for 12 weeks.
NSSOC included collagenase, hydrogels, medical grade honey, and non-active dressings. Surgical or mechanical debridement were not allowed. Compression wraps were mandatory throughout the study for all arms.
Post-hoc analyses assessed incidence and time to complete debridement, complete granulation and WBP in patients treated with BBD compared to Collagenase. WBP was defined as complete debridement and complete granulation, both assessed clinically. Log-rank test was used to compare survival distributions and Fisher Exact test to compare incidence rates.

The ChronEx Study

Of the 119 patients randomized, 46 were treated with BBD, 43 with placebo and 30 with NSSOC. Of the NSSOC arm, 8 patients were treated with Collagenase. Baseline characteristics were comparable between the BBD and Collagenase groups. The average wound size was 13.3 cm^2 (SD 20.4) and 10.3 cm^2 (SD 5.7), average non-viable tissue was 72.2% (SD 13.7) and 78.1% (SD 15.8), and average wound age was 26.8 weeks (SD 20.5) and 29.1 weeks (SD 27.9), on BBD and Collagenase, respectively.

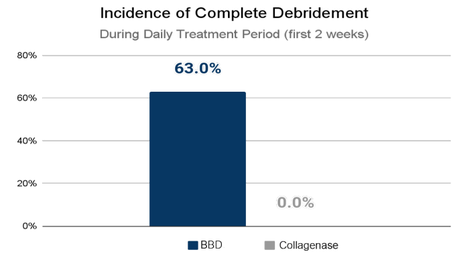


The Data

Summary of Efficacy and Safety Results

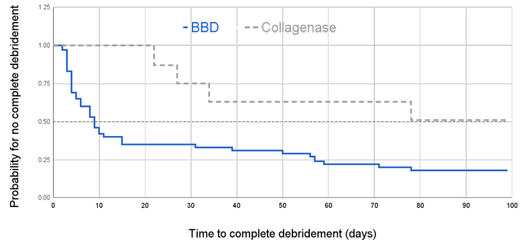
Parameter	BBD (n=46)	Collagenase (n=8)	p-value
Incidence of complete debridement (daily treatment period)	63%	0%	0.001
Median time for complete debridement	9 days	Not achieved	0.023
Incidence of WBP (daily treatment period)	50.0%	0%	0.015
Incidence of WBP (throughout study)	78.3%	37.5%	0.03
Estimated median time to achieve WBP	11 days	Not achieved	0.014
Incidence of complete wound closure	32.6%	25.0%	NSS
Average time to wound closure	48.4 days	76 days	0.05
Patient reported applicational pain	Comparable		N/A
Incidence of adverse wound reactions	Comparable		N/A

BBD was Superior to Collagenase in Complete Debridement Within Two Weeks



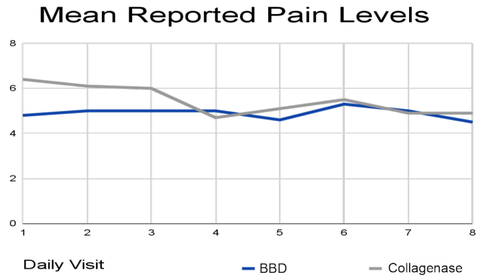
Incidence of CD (95% CI) during the two weeks daily treatment was 63.0% (47.5-76.8) for BBD vs. 0% for Collagenase (p=0.001)

BBD was Faster than Collagenase in Complete Debridement



Median time to complete debridement (95% CI) was 9 days (5-15 days) for BBD vs. not achieved for Collagenase (22-NA, P=0.023)

Comparable Applicational Pain on BBD vs. Collagenase



Conclusions

Debridement of non-viable tissue and promotion of a healthy well vascularized granulation tissue are key components of WBP, that can support secondary healing or facilitate the effectiveness of other advanced measures.

Head-to-Head post-hoc analyses based on the ChronEx Phase II RCT demonstrate:

- Superiority of EscharEx®, a bromelain-based gel vs. SANTYL®, a collagenase ointment, in wound debridement, promotion of granulation tissue, and time to wound closure in patients with chronic venous leg ulcers (VLU)
- Comparable safety profile and patient reported application pain on EscharEx vs. SANTYL

These data validate the design and outcomes of the Phase III study with EscharEx in VLU, targeted for H2 2024

CASE STUDIES