Procedures	Screening (Up to 1 wk)	Randomized (Wk 1, V1)	Treatment (Weeks 2-12) ^a	End of Treatment	Healing Confirmation
Informed consent	Χ				
Inclusion/exclusion	X	X			
Vital signs	Χ	X	X	Χ	
Screening labs	X				
Medical history	X				
Physical examination	Χ	As needed	As needed	As needed	
Wound history	X				
/ascular assessment	X				
Concomitant antibiotics	X	X	X	Χ	Χ
Demographics	X				
Wound assessment	X	X	X	Χ	Χ
Infection assessment	X	X	X	Χ	Χ
Off-loading assessment	X	X	X	Χ	
Participant education	X	X	X	Χ	Χ
Participant compliance			X	Χ	Χ
Randomization		X			
Aurix and UCC		X	X		
JCC only	X	X	X		
Assess adverse events		X	X	Χ	Χ
W-QOL		X		Χ	
Assess wound closure			Χ	Χ	
Confirm wound closure					Χ

Abbreviations: UCC, usual and customary care; W-QOL, Quality of Life with Chronic Wounds short-form instrument.

"If wound closure is not confirmed at week 12 for subjects treated with Aurix but with improved healing, treatment may continue for a maximum of 20 weeks from Wk1 at the discretion of the patient and treating clinician.