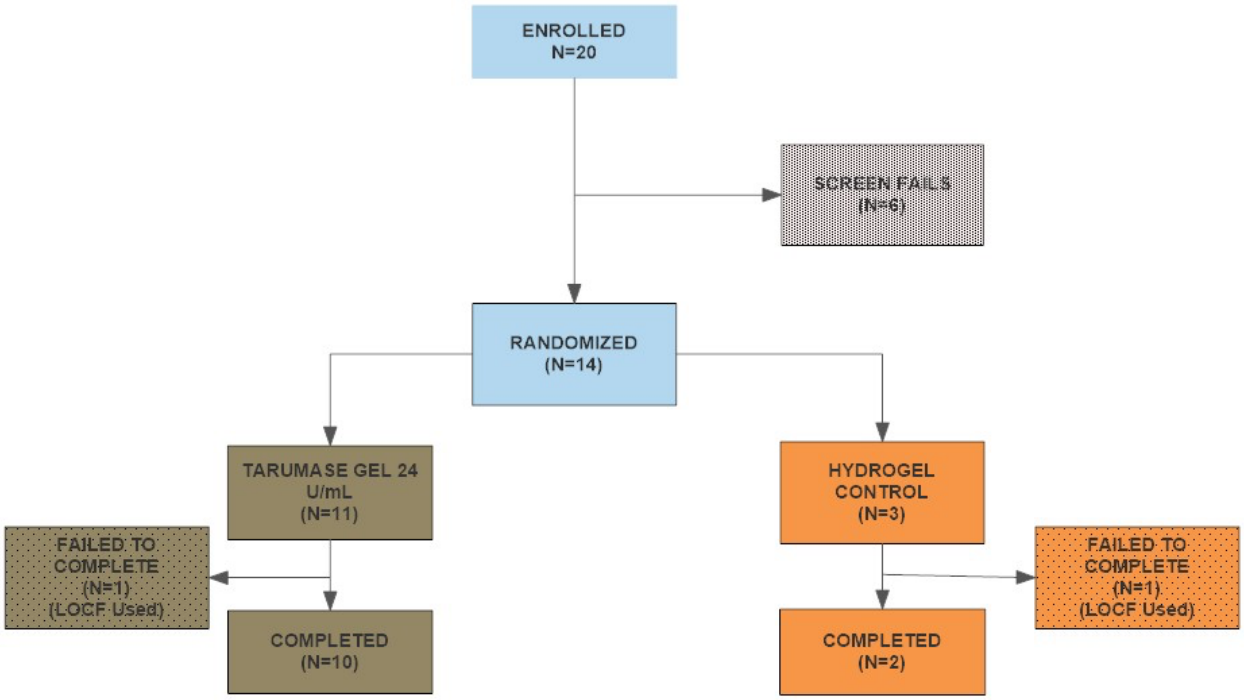
Participant Flow



Baseline Characteristics

	AWG 24U/mL (n=11)	Control (ActivHeal) (n=3)	P-value
Age			
Mean ± SD	60.5 ± 15.9	77 ± 5.7	0.1 (NS)
Median	64	77	
Range	40 – 87	67 – 86	
Sex			
Male (%)	54.5%	100%	0.3 (NS)
Female (%)	45.5%	0%	
Race			
Caucasian (%)	91%	100%	-
Asian Indian (%)	9%	0%	
BMI			
Mean ± SD	37.4 ± 13.6	28.3 ± 11.3	0.4 (NS)
Median	35	29	
Range	19 – 63	20 – 36	
Baseline Wound Size (cm^2)			
Mean ± SD	9.8 ± 6.6	4.0 ± 1.3	0.3 (NS)
Median	11.2	3.7	
Range	2.3 – 20.9	2.8 – 5.4	
Baseline Slough as a Proportion of Wound Size (%)			
Mean ± SD	70.7% ± 19.7	80.8% ± 16.7	-
Median	65.2	85.7	
Range	46.3 – 100	62.2 – 94.4	
Baseline Slough Area (cm^2)			
Mean ± SD	6.9 ± 5.0	3.3 ± 1.6	-
Median	5.7	2.4	
Range	1.5 – 16.3	2.3 – 5.1	
Wound Age (months)			
Mean ± SD	12.2 ± 6.8	11.0 ± 6.9	0.9 (NS)

	AWG 24U/mL (n=11)	Control (ActivHeal) (n=3)	P-value
Median	11	7	
Range	3 – 22	7 – 19	

Outcome Measures

Primary Outcome Measures

1. Pain NRS before dressings removed

	AWG (24U/mL) (N=11)	Control (N=3)
Baseline V2 (Mean)	3.4	1.3
Change from Baseline (Between Visits)**		
Visit 3	-1.1	-0.6
Visit 4	-0.6	-0.6
Visit 5	-1.3	-0.3
Visit 6	-1.1	+0.3
Visit 7	-2.1	-1.3
Visit 8	-2.0	-1.0
Visit 9	-1.8	-1.3
Visit 10	-1.7	-1.3
Visit 11	-1.7	-1.0
Visit 12	-1.7	-1.0
Visit 13	-1.8	-1.0
** Change from baseline is calculated for each visit compared to the mean baseline (i.e. Mean pain at baseline – Mean pain at visit). Negative (-) numbers have been used to indicate a **reduction** in pain score compared to baseline. Positive numbers indicate an **increase** in pain score compared to baseline.		

Pain NRS 15 minutes after application of Aurase Wound Gel (ITT Population)

	AWG (24 U/mL) (N=11)	Control (N=3)
Baseline V2 (Pre-dose)	3.4	1.3
Change from Baseline (15 to 30 minutes post-dose)**		
Visit 2 (Post-dose)	-0.6	-0.6
Visit 3	-1.9	-1.0
Visit 4	-1.4	-1.3
Visit 5	-1.5	-1.3
Visit 6	-1.5	-1.3
Visit 7	-2.3	-1.3
Visit 8	-2.3	-1.3
Visit 9	-1.9	-1.3
Visit 10	-2.2	-1.3

	AWG (24 U/mL) (N=11)	Control (N=3)
Visit 11	-2.3	-1.3
Visit 12	-2.4	-1.3
** Change from baseline is calculated for each visit compared to the mean baseline (i.e. Mean pain at baseline – Mean pain at visit). Negative (-) numbers have been used to indicate a **reduction** in pain score compared to baseline. Positive (+) numbers indicate an **increase** in pain score compared to baseline.		

Secondary Outcome Measures

1. Proportion of patients achieving "complete debridement"

Parameter	AWG (24 U/mL)	Control
≥ 90% debridement	3/11 (27.3%)	0/3 (0%)
≥ 80% debridement	5/11 (45.5%)	0/3 (0%)
≥ 70% debridement	6/11 (54.5%)	0/3 (0%)
≥ 60% debridement	6/11 (54.5%)	0/3 (0%)
≥ 50% debridement	7/11 (63.6%)	0/3 (0%)

2. Mean/median reduction in slough and eschar content

Timepoint	Statistic	AWG (24 U/mL) (N=11)	Control (N=3)
Baseline (V2)	Mean	6.9 ± 5.0 cm^2	3.3 ± 1.6 cm^2
	Median	5.7 cm^2	2.4 cm^2
1 Week (V4)	Mean	5.7 ± 5.1 cm^2	3.1 ± 1.7 cm^2
	Median	3.1 cm^2	2.3 cm^2
2 Weeks (V7)	Mean	4.2 ± 4.1 cm^2	3.0 ± 1.4 cm^2
	Median	2.1 cm^2	2.4 cm^2
3 Weeks (V10)	Mean	3.2 ± 3.5 cm^2	2.9 ± 1.0 cm^2
	Median	1.4 cm^2	2.7 cm^2
4 Weeks (V13)	Mean	2.6 ± 3.3 cm^2	3.3 ± 1.3 cm^2
	Median	1.1 cm^2	3.4 cm^2

3. Time to achieve complete debridement

	AWG (24 U/mL) (N=11)	Control (N=3)
Mean (±SD)	0.166 cm^2/day ± 0.110	-0.005 cm^2/day ± 0.033
Median	0.173 cm^2/day	0.007 cm^2/day
* Rate was calculated as the change in slough area from baseline to Day 26 divided by 26 days		

4. Proportion of granulation tissue

Timepoint	Statistic	AWG (24 U/mL) (N=11)	Control (N=3)
Baseline (V2)	Mean / Median	0.0%	0 .0%
1 Week (V4)	Mean	18.1 ± 13.2 %	5.0 ± 8.3%
	Median	17.1%	2.7%
2 Weeks (V7)	Mean	33.3 ± 19.5%	5.7 ± 8.5%
	Median	39.0%	5.6%
3 Weeks (V10)	Mean	44.7 ± 20.0%	7.9 ± 16.5%
	Median	39.0%	14.3%
4 Weeks (V13)	Mean	49.4 ± 21.2%	-2.3 ± 26.1%
	Median	45.9%	11.1%

5. Linear wound healing rates

Timepoint	Statistic	AWG (24 U/mL) (N=11)	Control (N=3)
Baseline Area	Mean	9.8 ± 6.6cm^2	4.0 ± 1.3cm^2
	Median	11.2 cm^2	3.7 cm^2
Run-in	Mean	0.004 ± 0.097cm^2/day	0.010 ± 0.055 cm^2/day
	Median	-0.01 cm^2/day	-0.01 cm^2/day
	p-value	>0.9 [NS]	
2 Weeks	Mean	0.226 ± 0.198 cm^2/day	0.028 ± 0.017 cm^2/day
	Median	0.108 cm^2/day	0.033 cm^2/day
	p-value	**0.028**	
4 Weeks	Mean	0.190 ± 0.177 cm^2/day	0.013 ± 0.022 cm^2/day
	Median	0.138 cm^2/day	0.019 cm^2/day
	p-value	**0.019**	

6. Mean/median surface area reduction

Timepoint	Statistic	AWG (24 U/mL) (N=11)	Control (N=3)
Baseline (V2)	Mean	9.8 ± 6.6	4.0 ± 1.3
	Median	11.2	3.7
1 Week (V4)	Mean	8.7 ± 6.8	3.6 ± 1.6
	Median	8.9	3.2
2 Weeks (V7)	Mean	7.2 ± 6.6	3.6 ± 1.4
	Median	4.7	3.6
3 Weeks (V10)	Mean	5.9 ± 5.7	3.3 ± 1.0
	Median	3.0	3.3
4 Weeks (V13)	Mean	5.0 ± 5.1	3.6 ± 1.2
	Median	3.0	4.0

7. Wound QoL

Parameter	Composite QOL Score	
	AWG (24 U/mL)	Control
"Body" Sub-scale (Q #1-#5)		
Mean Score (Baseline)	7.36	5.00
Mean Score (4 weeks)	5.09	4.33
Difference*	-2.27	-0.67
"Psyche" Sub Scale (Q #6 - #10)		
Mean Score (Baseline)	11.73	8.00
Mean Score (4 weeks)	7.82	9.33
Difference	-3.91	+1.33
"Everyday Life" Sub Scale (Q #11 - #16)		
Mean Score (Baseline)	10.00	1.00
Mean Score (4 weeks)	7.54	1.17
Difference	-2.46	+1.00
Total Score (Q #1 - #17)		
Mean Score (Baseline)	30.64	19.33
Mean Score (4 weeks)	20.70	21.67

Parameter	Composite QOL Score	
	AWG (24 U/mL)	Control
Difference	-9.94	+2.34
p-value	0.14 [NS]	
*Difference (Post-treatment – Baseline)		

Adverse Events

Summary of Participants with Treatment Emergent Adverse Events (TEAE)

	AWG (24 U/mL) (N=11)	Control (N=3)	Overall (N=14)
Participants With any AE	5 (45.4%)	2 (66.6%)	7 (50%)
Total AEs	10	3	13
Total TEAEs	7	3	10
Total of Serious TEAEs	1	0	1
Death due to TEAEs	0	0	0
Withdrawal due to TEAEs	1	1	2

Types of AEs

Number of Participants (%)**	AWG (24U/mL) (N=11)	Control (N=3)
Participants with AEs	**5 (45.54)**	**2 (66.6%)**
Number of TEAEs	7	3
Suspected Related♣	1	0
TEAEs by SOC (MedDRA PT)		
[SOC] Skin and Subcutaneous Tissue Disorders		
Skin Maceration	0/3 (0%)	1/3 (33.3%)
Skin Wound	1/11 (9.1%)	0/3 (0%)
[SOC] Infections and Infestations		
Viral Meningitis	1/11 (9.1%)	0/3 (0%)
Wound Infection	3/11 (27.3%)	0/3 (0%)
[SOC] Musculoskeletal Disorders		
Joint Instability	0/11 (0%)	1/3 (33/3%)
[SOC] Injury, Poisoning and Procedural Complications		
Discomfort	0/11 (0%)	1/3 (33.3%)
[SOC] General Disorders and Administration Site Conditions		
Application Site Pain	1/11 (9.1%)	0/3 (0%)
** Multiple occurrences of an AE at sites receiving the same treatment in one patient is counted as one AE ♣ Related = “possibly”, “probably” or “almost definitely” related		