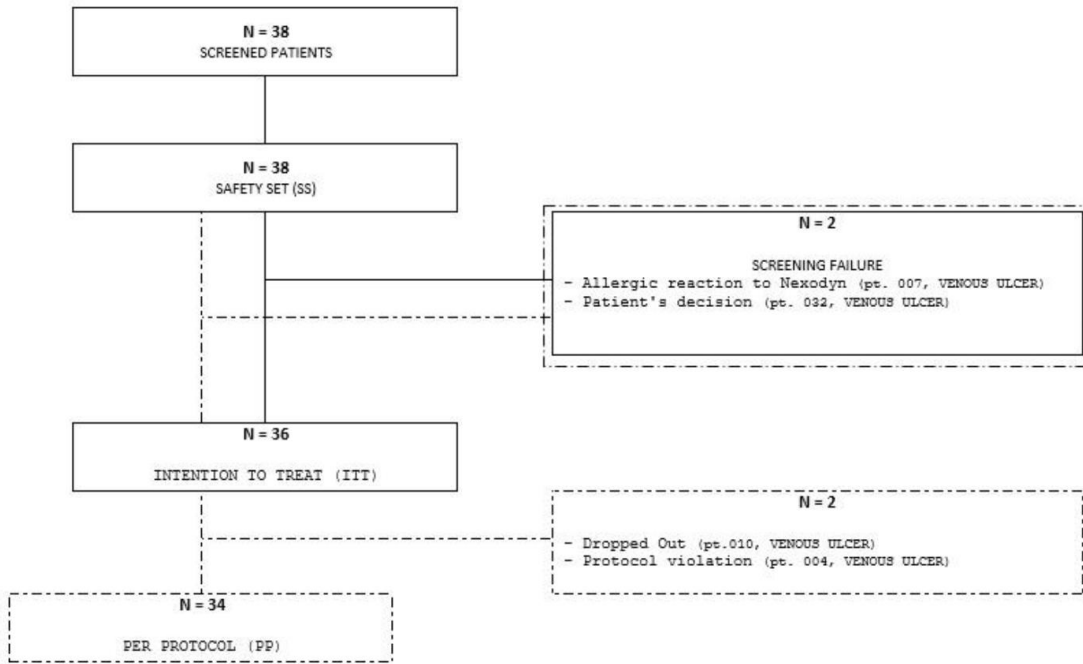


Participant flow



Baseline characteristics

Summary of demographic characteristics			
Analysis Set: Intention To Treat			
Age (years)	N		36
	Mean		74.8
	Standard Deviation		12.29
	Median		80.0
	Minimum		41.0
	Maximum		91.0
Sex	Female	n	26
		%	72.2%
	Male	n	10
		%	27.8%
BMI (Kg/m2)	N		36
	Mean		26.7
	Standard Deviation		4.99
	Median		26.1
	Minimum		18.4
	Maximum		38.3
Race	Caucasian	n	35
		%	97.2%
	Black	n	1
		%	2.8%
	Asian	n	0
		%	0.0%
	Other	n	0
		%	0.0%

Table DEMO_S (ITT): Produced by HR on 14.09.2018

Summary of demographic characteristics			
Analysis Set: Per Protocol			
Age (years)	N		34
	Mean		75.1
	Standard Deviation		12.35
	Median		80.0
	Minimum		41.0
	Maximum		91.0
Sex	Female	n	25
		%	73.5%
	Male	n	9
		%	26.5%
BMI (Kg/m2)	N		34
	Mean		26.5
	Standard Deviation		5.03
	Median		26.0
	Minimum		18.4
	Maximum		38.3
Race	Caucasian	n	33
		%	97.1%
	Black	n	1
		%	2.9%
	Asian	n	0
		%	0.0%
	Other	n	0
		%	0.0%

Table DEMO_S (PP): Produced by HR on 14.09.2018

**Summary of area and volume of the ulcer at baseline
(by type of ulcer)
Analysis Set: Intention To Treat**

		Type of ulcer	
		Venous	Atypical
Ulcer area (cm2)	N	31	5
	Mean	16.9	8.9
	Standard Deviation	21.66	1.97
	Median	8.6	8.5
	Minimum	5.0	6.0
	Maximum	96.6	11.2
Ulcer volume (mm3)	N	31	5
	Mean	2229.0	260.0
	Standard Deviation	10404.84	207.36
	Median	100.0	300.0
	Minimum	0.0	0.0
	Maximum	58200.0	500.0

Table SIZE_S (type,ITT): Produced by HR on 19.09.2018

**Summary of area and volume of the ulcer at baseline
(by type of ulcer)
Analysis Set: Per Protocol**

		Type of ulcer	
		Venous	Atypical
Ulcer area (cm2)	N	29	5
	Mean	16.7	8.9
	Standard Deviation	22.03	1.97
	Median	8.6	8.5
	Minimum	5.1	6.0
	Maximum	96.6	11.2
Ulcer volume (mm3)	N	29	5
	Mean	2286.2	260.0
	Standard Deviation	10762.82	207.36
	Median	100.0	300.0
	Minimum	0.0	0.0
	Maximum	58200.0	500.0

Table SIZE_S (type,PP): Produced by HR on 19.09.2018

Outcome measures

Summary of first occurrence of A1, A2, A3 or B1 at WBP scale (or healing)
within the 4 weeks of Nexodyn treatment
Analysis Set: Intention To Treat (n=36)

	n	%
No	7	19.4%
Yes	29	80.6%

Table WBP1_S (ITT): Produced by HR on 26.09.2018

Summary of first occurrence of A1, A2, A3 or B1 at WBP scale (or healing)
within the 4 weeks of Nexodyn treatment
(by type of ulcer)
Analysis Set: Intention To Treat (n=36)

	Type of ulcer			
	Venous ulcer		Atypical ulcer	
	n	%	n	%
No	7	22.6%	0	0.0%
Yes	24	77.4%	5	100.0%

Table WBP1_S (type,ITT): Produced by HR on 26.09.2018

$p = 0.558991$

Summary of first occurrence of A1, A2, A3 or B1 at WBP scale (or healing)
within the 4 weeks of Nexodyn treatment
Analysis Set: Per Protocol

	n	%
No	6	17.6%
Yes	28	82.4%

Table WBP1_S (PP): Produced by HR on 26.09.2018

Summary of first occurrence of A1, A2, A3 or B1 at WBP scale (or healing)
within the 4 weeks of Nexodyn treatment
(by type of ulcer)
Analysis Set: Per Protocol

	Type of ulcer			
	Venous ulcer		Atypical ulcer	
	n	%	n	%
No	6	20.7%	0	0.0%
Yes	23	79.3%	5	100.0%

Table WBP1_S (type,PP): Produced by HR on 26.09.2018

$p = 0.558500$

Adverse events

Summary of adverse events, by SOC and PT
Analysis Set: Safety Set (n=38)

		N
Patients with at least one AE		4
Total number of AEs		9
10018065 General disorders and administration site conditions	Patients with at least one AE (per SOC)	3
	Total adverse events (PT)	7
	10003041 Application site erythema	2
	10003051 Application site pain*	2
	10003053 Application site pruritus	2
	10037660 Pyrexia	1
10021881 Infections and infestations	Patients with at least one AE (per SOC)	1
	Total adverse events (PT)	1
	10021784 Infected skin ulcer	1
10028395 Musculoskeletal and connective tissue disorders	Patients with at least one AE (per SOC)	1
	Total adverse events (PT)	1
	10003239 Arthralgia	1

Table ADEV_5: Produced by HR on 28.09.2018

* these events are reported by the Investigator as *application site pain* and *application site burning*. The same events are reported by the pharmacovigilance as a two (2) different events of *application site pain*.