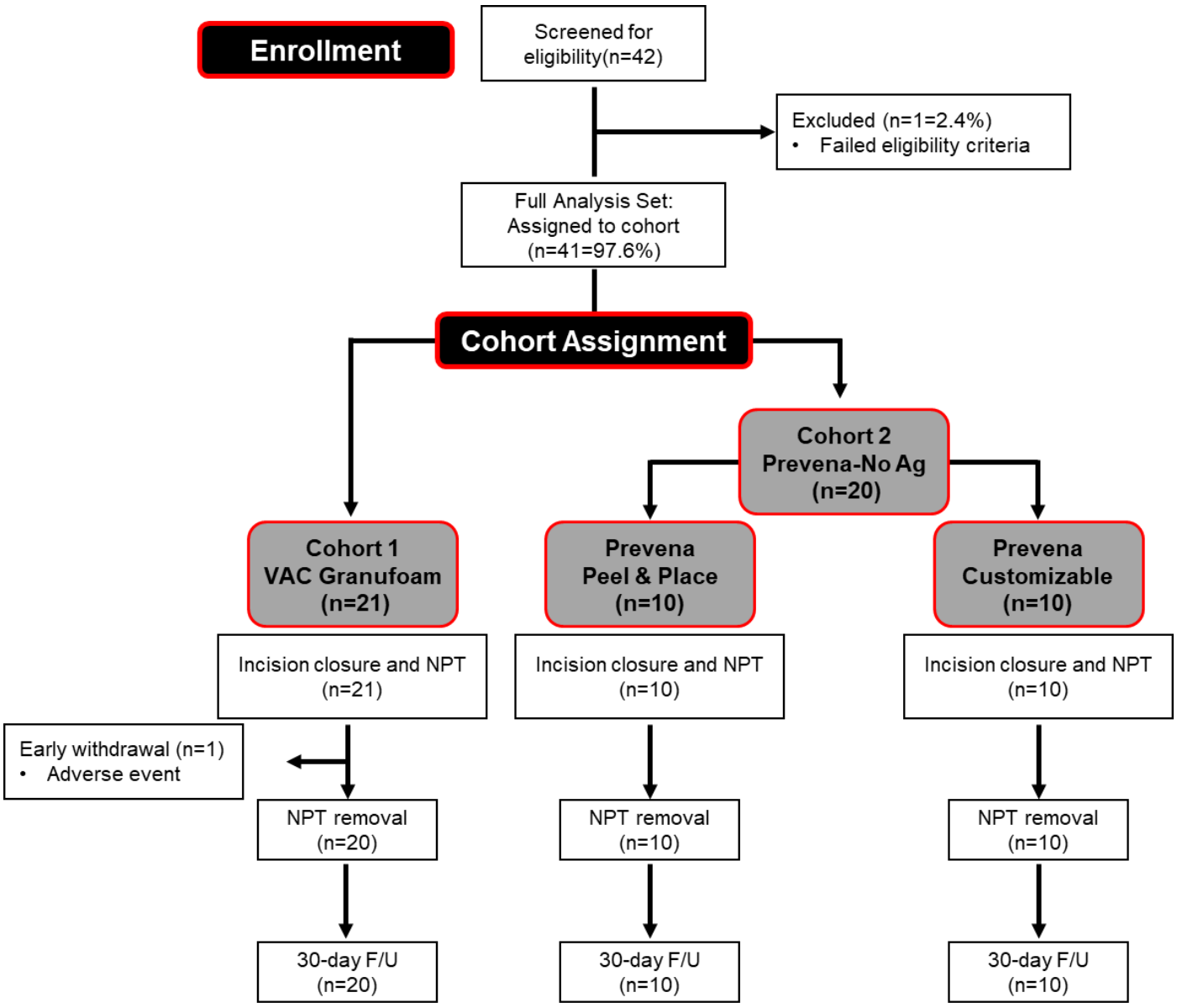
Participant Flow



Baseline Characteristics: Table 1

	Treatment (Prevena) N=20	Control (VAC) N=21	Overall N=41
Age (years)			
n	20	21	41
Mean (Std Dev)	49.0 (18.11)	55.8 (16.14)	52.5 (17.26)
Median	46.5	59.0	55.0
Min, Max	26.0, 77.0	29.0, 78.0	26.0, 78.0
Sex n (%)			
Female	16 (80%)	13 (62%)	29 (71%)
Male	4 (20%)	8 (38%)	12 (29%)
Race n (%)			
American Indian or Alaskan Native	0 (0%)	0 (0%)	0 (0%)
Native Hawaiian or Other Pacific Islander	0 (0%)	0 (0%)	0 (0%)
Asian	1 (5%)	1 (5%)	2 (5%)
Black or African American	3 (15%)	2 (10%)	5 (12%)
White	14 (70%)	14 (67%)	28 (68%)
Other	1 (5%)	2 (10%)	3 (7%)
Not Done	1 (5%)	2 (10%)	3 (7%)
Ethnicity n (%)			
Hispanic or Latino	0 (0%)	0 (0%)	0 (0%)
Not Hispanic/Not Latino	12 (60%)	12 (57%)	24 (59%)
Not Reported	0 (0%)	5 (24%)	5 (12%)
Unknown	8 (40%)	4 (19%)	12 (29%)
Height (cm)			
N	20	21	41
Mean (Std Dev)	165.1 (9.15)	166.7 (6.71)	165.9 (7.93)
Median	163.0	168.0	165.0
Min, Max	152.0, 181.0	157.0, 176.0	152.0, 181.0
Weight (kg)			
N	20	21	41
Mean (Std Dev)	79.0 (14.97)	81.8 (14.55)	80.4 (14.64)
Median	79.0	80.0	80.0
Min, Max	54.0, 106.0	55.0, 103.0	54.0, 106.0
Body Mass Index (kg/m^2)			
N	20	21	41
Mean (Std Dev)	28.9 (4.27)	29.4 (4.66)	29.1 (4.43)
Median	29.5	29.1	29.1
Min, Max	21.1, 34.6	21.8, 41.8	21.1, 41.8

Outcome Measures

Table 2. Summary of Treatment-related Treatment-emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term – Safety Analysis Set

	Cohort 1 Control (VAC) N=21		**Cohort 2** Treatment (Prevena) N=20	
	Events	Subjects (%)	Events	Subjects (%)
Subjects with at least one Treatment Related TEAE	3	3 (14%)	4	4 (20%)
Immune system disorders	1	1 (5%)	1	1 (5%)
Hypersensitivity	0	0 (0%)	1	1 (5%)
Skin reaction	1	1 (5%)	0	0 (0%)
Skin and subcutaneous tissue disorders	2	2 (10%)	3	3 (15%)
Blister	1	1 (5%)	3	3 (15%)
Skin abrasion	1	1 (5%)	0	0 (0%)

Table 3. Summary of Treatment-related Treatment-emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term – Safety Analysis Set

	Cohort 1		**Cohort 2**			
	V.A.C. Granufoam N=21		Prevena Peel and Place 20cm N=10		Prevena Customizable N=10	
	Events	Subjects (%)	Events	Subjects (%)	Events	Subjects (%)
Subjects with at least one Treatment Related TEAE	3	3 (14%)	3	3 (30%)	1	1 (10%)
Immune system disorders	1	1 (5%)	0	0 (0%)	1	1 (10%)
Hypersensitivity	0	0 (0%)	0	0 (0%)	1	1 (10%)
Skin reaction	1	1 (5%)	0	0 (0%)	0	0 (0%)
Skin and subcutaneous tissue disorders	2	2 (10%)	3	3 (30%)	0	0 (0%)
Blister	1	1 (5%)	3	3 (30%)	0	0 (0%)
Skin abrasion	1	1 (5%)	0	0 (0%)	0	0 (0%)

Table 4. Duration of Dressing Wear Period (ie. Treatment Period) and Study Period

		Cohort 2 Treatment (Prevena) (n=20)	Cohort 1 Control (VAC) (n=21)	Total (n=41)
Variable Description	**Values**			
Duration of Dressing Wear Prior to End of Treatment (Days)	N	20	21	41
	Mean	5.5	5.43	5.46
	SD	0.946	0.676	0.809
	Median	5	5	5
	Min	4	4	4
	Max	8	7	8
Time Elapsed Prior to End of Follow-Up (Days)	N	20	21	41
	Mean	39.95	32.71	36.24
	SD	13.539	5.909	10.86
	Median	38.5	31	32
	Min	26	27	26
	Max	72	54	72

Adverse Events

Table 5. Summary of All Treatment-emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term – Safety Analysis Set

	Cohort 1 Control (VAC) N=21		**Cohort 2** Treatment (Prevena) N=20	
	Events	Subjects (%)	Events	Subjects (%)
Subjects with at least one TEAE	5	5 (24%)	9	8 (40%)
Cardiac disorders	0	0 (0%)	1	1 (5%)
Tachycardia	0	0 (0%)	1	1 (5%)
Immune system disorders	1	1 (5%)	1	1 (5%)
Hypersensitivity	0	0 (0%)	1	1 (5%)
Skin reaction	1	1 (5%)	0	0 (0%)
Infections and infestations	0	0 (0%)	3	2 (10%)
Wound infection	0	0 (0%)	3	2 (10%)
Injury, poisoning and procedural complications	1	1 (5%)	0	0 (0%)
Wound secretion	1	1 (5%)	0	0 (0%)
Pregnancy, puerperium and perinatal conditions	0	0 (0%)	1	1 (5%)
Postpartum haemorrhage	0	0 (0%)	1	1 (5%)
Renal and urinary disorders	1	1 (5%)	0	0 (0%)
Urinary retention	1	1 (5%)	0	0 (0%)
Skin and subcutaneous tissue disorders	2	2 (10%)	3	3 (15%)
Blister	1	1 (5%)	3	3 (15%)
Skin abrasion	1	1 (5%)	0	0 (0%)