Table 39.AH3: Analysis of Change from Baseline in Oswestry Disability Index (ODI) by Visit (ITT Population) 2
Table 42.AH3: Secondary Analysis: Change from Baseline in Visual Analog Scale (VAS) by Visit (ITT Population) 4
Table 48.AH3: Healthcare Utilization Outcomes (ITT Population) 6

Table 39.AH3: Analysis of Change from Baseline in Oswestry Disability Index (ODI) by Visit
(ITT Population)
(Page 1 of 2)

	RF Ablation Arm (N=66)	Control Arm (N=74)
Baseline ODI Total Score		
N	66	74
Mean	44.7	46.9
SD	11.30	11.67
Median	40.0	46.0
Min. to Max.	30 to 76	30 to 88
3 Month[a] ODI Total Score		
N	66	74
Mean[b]	21.0	42.3
SD[b]	15.95	15.81
Median[b]	18.8	40.5
Min. to Max.[b]	0 to 62	7 to 75
ODI Total Score Change from Baseline to 3 Month[a]		
N	66	74
Mean[b]	-23.7	-4.6
SD[b]	17.96	15.01
Median[b]	-25.6	-2.1
Min. to Max.[b]	-70 to 12	-64 to 29
Paired t-test P-value[c]	<0.001	

Mean (95% Confidence Interval)[d]	-23.7 (-27.7 to -19.7)	-4.6 (-9.0 to -0.2)
Difference from Control Arm in Means (95% Confidence Interval)[d]	-19.0 (-24.9 to -13.1)	
ANOVA P-value[d]	<0.001	

[a] Multiple imputation used to impute missing values. Values have been adjusted for multiple imputation.

[b] Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset.

[c] P-value from a paired t-test on the RF Ablation Arm.

[d] Estimates and p-value from an ANOVA with a factor of treatment group.

Note: Visits are computed as post-treatment for the RF Ablation Arm, and post-randomization for the Control Arm.

SOURCE: RTANIS\Relievant\CIP_0006\12_Month_Analysis\Analysis\iprim_ah3 (Mar 5, 2021 12:42)

Table 39.AH3: Analysis of Change from Baseline in Oswestry Disability Index (ODI) by Visit
(ITT Population)
(Page 2 of 2)

	RF Ablation Arm (N=66)	Control Arm (N=74)
6 Month (RF Ablation Arm)/Last Attended Visit (Control Arm) ODI Total Score		
N	61	72
Mean	19.1	44.8
SD	15.38	14.30
Median	16.0	46.0
Min. to Max.	0 to 56	6 to 76
ODI Total Score Change from Baseline to 6 Month (RF Ablation Arm)/Last Attended Visit (Control Arm)		
N	61	72
Mean	-25.1	-2.4
SD	17.35	14.29
Median	-24.0	-1.0
Min. to Max.	-60 to 6	-62 to 20
Paired t-test P-value[c]	<0.001	
Mean (95% Confidence Interval)[d]	-25.1 (-29.1 to -21.1)	-2.4 (-6.1 to 1.2)
Difference from Control Arm in Means (95% Confidence Interval)[d]	-22.7 (-28.1 to -17.3)	
ANOVA P-value[d]	<.0001	

[a] Multiple imputation used to impute missing values. Values have been adjusted for multiple imputation.

[b] Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset.

[c] P-value from a paired t-test on the RF Ablation Arm.

[d] Estimates and p-value from an ANOVA with a factor of treatment group.

Note: Visits are computed as post-treatment for the RF Ablation Arm, and post-randomization for the Control Arm.

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Table 42.AH3: Secondary Analysis: Change from Baseline in Visual Analog Scale (VAS) by Visit
(ITT Population)
(Page 1 of 2)

	RF Ablation Arm (N=66)	Control Arm (N=74)
3 Month VAS Score		
N	66	51
Mean	3.21	5.77
SD	2.692	2.157
Median	2.50	6.00
Min. to Max.	0.0 to 10.0	0.0 to 10.0
VAS Score Change from Baseline to 3 Month		
N	66	51
Mean	-3.53	-1.06
SD	2.627	2.067
Median	-4.00	-1.00
Min. to Max.	-8.0 to 2.0	-6.5 to 3.0
Paired t-test P-value[a]	<0.001	
Mean (95% Confidence Interval)[b]	-3.53 (-4.11 to -2.94)	-1.06 (-1.73 to -0.40)
Difference from Control Arm in Means (95% Confidence Interval)[b]	-2.47 (-3.35 to -1.58)	
ANOVA P-value[b]	<0.001	
VAS Responder Rates		
Subjects with ≥ 1.5-point VAS decrease	49 (74.2%)	18 (35.3%)
Fisher's Exact Test P-value	<0.001	
Subjects with ≥ 2.0-point VAS decrease	48 (72.7%)	17 (33.3%)
Fisher's Exact Test P-value	<0.001	

[a] P-value from a paired t-test on the RF Ablation Arm.

[b] Estimates and p-value from ANOVA with a factor of treatment group.

Note: Visits are computed as post-treatment for the RF Ablation Arm, and post-randomization for the Control Arm.

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Table 42.AH3: Secondary Analysis: Change from Baseline in Visual Analog Scale (VAS) by Visit
(ITT Population)
(Page 2 of 2)

	RF Ablation Arm (N=66)	Control Arm (N=74)
6 Month (RF Ablation Arm)/Last Attended Visit (Control Arm) VAS Score		
N	60	70
Mean	3.13	6.46
SD	2.442	1.782
Median	3.00	7.00
Min. to Max.	0.0 to 8.0	1.0 to 10.0
VAS Score Change from Baseline to 6 Month (RF Ablation Arm)/Last Attended Visit (Control Arm)		
N	60	70
Mean	-3.54	-0.37
SD	2.506	1.935
Median	-4.00	0.00
Min. to Max.	-8.0 to 1.0	-7.0 to 4.0
Paired t-test P-value[a]	<0.001	
Mean (95% Confidence Interval)[b]	-3.54 (-4.11 to -2.98)	-0.37 (-0.90 to 0.15)
Difference from Control Arm in Means (95% Confidence Interval)[b]	-3.17 (-3.94 to -2.40)	
ANOVA P-value[b]	<0.001	
VAS Responder Rates		
Subjects with ≥ 1.5-point VAS decrease	48 (80.0%)	12 (17.1%)
Fisher's Exact Test P-value	<0.001	
Subjects with ≥ 2.0-point VAS decrease	45 (75.0%)	12 (17.1%)
Fisher's Exact Test P-value	<0.001	

[a] P-value from a paired t-test on the RF Ablation Arm.

[b] Estimates and p-value from ANOVA with a factor of treatment group.

Note: Visits are computed as post-treatment for the RF Ablation Arm, and post-randomization for the Control Arm.

SOURCE: RTANIS\Relievant\CIP_0006\12_Month_Analysis\Analysis\isecvas_ah3 (Mar 5, 2021 13:13)

Table 48.AH3: Healthcare Utilization Outcomes
(ITT Population)

	RF Ablation Arm (N=66)	Control Arm (N=74)	P-value
Opioid Use			
n	65	52	
Subjects Not Taking Opioids at Baseline, Not Taking Opioids at 3 Months	43 (66.2%)	39 (75.0%)	0.394[a]
Subjects Not Taking Opioids at Baseline, Taking Opioids at 3 Months	3 (4.6%)	0	
Subjects Taking Opioids at Baseline, Not Taking Opioids at 3 Months	2 (3.1%)	1 (1.9%)	
Subjects Taking Opioids at Baseline, Taking Opioids at 3 Months	17 (26.2%)	12 (23.1%)	
n	61	66	
Subjects Not Taking Opioids at Baseline, Not Taking Opioids at 6 Months	40 (65.6%)	50 (75.8%)	0.560[a]
Subjects Not Taking Opioids at Baseline, Taking Opioids at 6 Months	2 (3.3%)	1 (1.5%)	
Subjects Taking Opioids at Baseline, Not Taking Opioids at 6 Months	4 (6.6%)	2 (3.0%)	
Subjects Taking Opioids at Baseline, Taking Opioids at 6 Months	15 (24.6%)	13 (19.7%)	
n	60		
Subjects Not Taking Opioids at Baseline, Not Taking Opioids at 9 Months	39 (65.0%)		0.655[b]
Subjects Not Taking Opioids at Baseline, Taking Opioids at 9 Months	2 (3.3%)		
Subjects Taking Opioids at Baseline, Not Taking Opioids at 9 Months	3 (5.0%)		
Subjects Taking Opioids at Baseline, Taking Opioids at 9 Months	16 (26.7%)		
n	61		
Subjects Not Taking Opioids at Baseline, Not Taking Opioids at 12 Months	40 (65.6%)		0.414[b]
Subjects Not Taking Opioids at Baseline, Taking Opioids at 12 Months	2 (3.3%)		
Subjects Taking Opioids at Baseline, Not Taking Opioids at 12 Months	4 (6.6%)		
Subjects Taking Opioids at Baseline, Taking Opioids at 12 Months	15 (24.6%)		

[a] P-value from a Chi-Square Test of Equal Proportions.

[b] P-value from a McNemar's test.

Note: Visits are computed as post-treatment for the RF Ablation Arm, and post-randomization for the Control Arm.

SOURCE: RTANIS\Relievant\CIP_0006\12_Month_Analysis\Analysis\ihlthut_ah3 (Mar 19, 2021 14:41)