

Table 14.2.9.1 Summary of Pure Tone Audiometric - by timepoint - FAS

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
Air conduction left ear (dbHL)							
Baseline							
n	33						
Mean (SD)	62.34 (16.51)						
Median	62.50						
Min; Max	25.8;105.0						
Month 6							
n	24	24	24	Absolute change	-0.17 (23)	0.868	(-3.72, 3.16)
Mean (SD)	62.98 (15.58)	-0.28 ( 8.15)	-0.04 (15.34)				
Median	63.80	0.10	0.12	% Change	-0.01 (23)	0.990	(-6.52, 6.44)
Min; Max	14.0;104.0	-20.0; 11.2	-45.7; 27.1				
Month 12							
n	31	31	31	Absolute change	-0.07 (30)	0.943	(-2.84, 2.65)
Mean (SD)	61.30 (15.65)	-0.10 ( 7.48)	0.41 (12.57)				
Median	61.30	-0.60	-1.13	% Change	0.18 (30)	0.859	(-4.20, 5.02)
Min; Max	20.0;101.3	-21.2; 21.2	-22.9; 37.7				
Month 18							
n	11	11	11	Absolute change	-1.91 (10)	0.085	(-11.9, 0.92)
Mean (SD)	58.12 (17.44)	-5.50 ( 9.56)	-8.54 (13.32)				
Median	55.00	-3.70	-6.43	% Change	-2.13 (10)	0.059	(-17.5, 0.41)
Min; Max	21.3; 87.5	-22.5; 5.5	-33.3; 8.2				
Month 24							
n	9	9	9	Absolute change	-0.15 ( 8)	0.882	(-5.19, 4.55)
Mean (SD)	62.63 (13.51)	-0.32 ( 6.33)	1.39 (10.05)				
Median	60.00	1.20	1.74	% Change	0.42 ( 8)	0.689	(-6.33, 9.12)
Min; Max	47.5; 92.5	-12.5; 7.9	-11.9; 17.1				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.

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				Change from baseline	t-value (df)	p-value	95% CI
Air conduction left ear (dbHL)							
Month 36							
n	7	7	7	Absolute change	-2.97 ( 6)	0.025	(-10.7,-1.03)
Mean (SD)	61.11(11.98)	-5.84( 5.20)	-8.52( 8.62)				
Median	57.50	-7.50	-10.2	% Change	-2.62 ( 6)	0.040	(-16.5,-0.55)
Min; Max	45.0; 79.0	-12.5; 1.9	-21.7; 3.6				
Month 48							
n	9	9	9	Absolute change	-1.39 ( 8)	0.202	(-11.0, 2.72)
Mean (SD)	56.53(15.74)	-4.13( 8.91)	-6.19(12.22)				
Median	56.70	-3.30	-5.60	% Change	-1.52 ( 8)	0.167	(-15.6, 3.20)
Min; Max	22.5; 77.5	-19.5; 10.5	-21.1; 15.7				
Last Observation							
n	33	33	33	Absolute change	-2.27 (32)	0.030	(-5.36,-0.29)
Mean (SD)	59.51(15.01)	-2.83( 7.14)	-3.79(10.70)				
Median	58.00	-2.50	-3.92	% Change	-2.04 (32)	0.050	(-7.58, 0.00)
Min; Max	22.5; 92.5	-22.5; 10.5	-33.3; 17.1				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.