

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 right ear (dbHL)							
Baseline							
n	33						
Mean (SD)	61.85(17.90)						
Median	60.00						
Min; Max	21.6; 96.3						
Month 6							
n	24	24	24	Absolute change	-0.52 (23)	0.605	(-4.86, 2.89)
Mean (SD)	62.23(15.83)	-0.98( 9.18)	0.18(14.44)				
Median	63.15	-1.25	-2.26	% Change	0.06 (23)	0.952	(-5.92, 6.28)
Min; Max	21.0; 98.0	-25.0; 16.2	-26.3; 47.9				
Month 12							
n	31	31	31	Absolute change	0.51 (30)	0.613	(-2.65, 4.42)
Mean (SD)	62.08(17.40)	0.88( 9.63)	2.72(14.81)				
Median	60.00	-0.60	-1.71	% Change	1.02 (30)	0.314	(-2.71, 8.16)
Min; Max	21.0;112.5	-26.3; 26.2	-28.0; 47.9				
Month 18							
n	11	11	11	Absolute change	-1.65 (10)	0.130	(-7.71, 1.15)
Mean (SD)	58.63(21.57)	-3.28( 6.59)	-5.36( 9.15)				
Median	57.50	-2.50	-6.18	% Change	-1.94 (10)	0.081	(-11.5, 0.79)
Min; Max	20.0;103.8	-14.0; 7.5	-21.7; 9.5				
Month 24							
n	10	10	10	Absolute change	0.05 ( 9)	0.964	(-11.0,11.45)
Mean (SD)	63.63(13.28)	0.23(15.68)	6.16(32.01)				
Median	62.00	2.50	4.23	% Change	0.61 ( 9)	0.558	(-16.7,29.07)
Min; Max	47.5; 92.5	-33.8; 30.2	-36.0; 89.3				

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 right ear							
(dbHL) Month 36							
n	7	7	7	Absolute change	-1.40 ( 6)	0.211	(-8.24, 2.24)
Mean (SD)	62.84(14.55)	-3.00( 5.67)	-4.45( 9.76)				
Median	58.00	-3.30	-3.82	% Change	-1.21 ( 6)	0.273	(-13.5, 4.57)
Min; Max	46.3; 83.0	-11.2; 5.0	-19.5; 10.5				
Month 48							
n	9	9	9	Absolute change	-1.81 ( 8)	0.108	(-12.2, 1.46)
Mean (SD)	54.32(12.85)	-5.37( 8.89)	-5.17(14.49)				
Median	55.00	-5.50	-8.09	% Change	-1.07 ( 8)	0.316	(-16.3, 5.97)
Min; Max	25.8; 74.0	-21.0; 6.5	-22.1; 19.4				
Last Observation							
n	33	33	33	Absolute change	-0.79 (32)	0.438	(-5.06, 2.25)
Mean (SD)	60.44(15.70)	-1.41(10.31)	0.54(20.19)				
Median	58.80	-1.20	-2.12	% Change	0.15 (32)	0.878	(-6.62, 7.70)
Min; Max	25.8;103.8	-33.8; 30.2	-36.0; 89.3				

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