

Table 14.2.20 Summary of MRI / MRS - 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
ADC White (10^-6mm2/s)							
Baseline							
n	9						
Mean (SD)	913.0(119.5)						
Median	886.0						
Min; Max	746; 1140						
Month 6							
n	9	9	9	Absolute change	2.1 (8)	0.070	(-5.8,121.2)
Mean (SD)	970.7(87.6)	57.7(82.6)	7.1(10.5)				
Median	972.0	44.0	5.1	% Change	2.1 (8)	0.074	(-0.9, 15.2)
Min; Max	840; 1085	-55; 228	-5; 31				
Month 12							
n	9	9	9	Absolute change	1.5 (8)	0.184	(-19.6, 86.5)
Mean (SD)	946.4(82.6)	33.4(69.0)	4.4(8.5)				
Median	936.0	39.0	4.9	% Change	1.5 (8)	0.160	(-2.1, 10.9)
Min; Max	834; 1063	-77; 177	-7; 24				
Month 18							
n	9	9	9	Absolute change	1.6 (8)	0.139	(-19.6,116.5)
Mean (SD)	961.4(67.4)	48.4(88.6)	6.3(9.5)				
Median	980.0	63.0	6.5	% Change	2.0 (8)	0.083	(-1.0, 13.5)
Min; Max	875; 1044	-144; 158	-13; 18				
Month 48							
n	9	9	9	Absolute change	-3.6 (8)	0.007	(-185,-40.8)
Mean (SD)	800.3(47.3)	-113(93.5)	-11.5(8.3)				
Median	782.0	-88.0	-10.1	% Change	-4.1 (8)	0.003	(-17.8, -5.1)
Min; Max	752; 897	-306; 12	-27; 2				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Parameters only valid for 9 subjects from rhLAMANO2.

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Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
ADC White (10^-							
6mm2/s) Last							
Observation							
n	9	9	9	Absolute change	-3.6 (8)	0.007	(-185,-40.8)
Mean (SD)	800.3(47.3)	-113(93.5)	-11.5(8.3)				
Median	782.0	-88.0	-10.1	% Change	-4.1 (8)	0.003	(-17.8, -5.1)
Min; Max	752; 897	-306; 12	-27; 2				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Parameters only valid for 9 subjects from rhLAMANO2.