

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 Grey (10^-6mm2/s)							
Baseline							
n	9						
Mean (SD)	796.9(37.1)						
Median	794.0						
Min; Max	749; 862						
Month 6							
n	9	9	9	Absolute change	0.2 (8)	0.812	(-62.3, 77.2)
Mean (SD)	804.3(91.5)	7.4(90.8)	1.0(11.4)				
Median	777.0	-14.0	-1.8	% Change	0.3 (8)	0.795	(-7.7, 9.8)
Min; Max	735; 1031	-73; 237	-9; 30				
Month 12							
n	9	9	9	Absolute change	-2.6 (8)	0.032	(-60.4, -3.6)
Mean (SD)	764.9(28.5)	-32.0(36.9)	-3.9(4.4)				
Median	756.0	-20.0	-2.6	% Change	-2.6 (8)	0.030	(-7.3, -0.5)
Min; Max	733; 808	-99; 14	-12; 2				
Month 18							
n	9	9	9	Absolute change	-1.0 (8)	0.358	(-68.8, 27.9)
Mean (SD)	776.4(44.0)	-20.4(62.9)	-2.3(7.6)				
Median	768.0	-21.0	-2.7	% Change	-0.9 (8)	0.381	(-8.2, 3.5)
Min; Max	728; 854	-130; 60	-15; 8				
Month 48							
n	9	9	9	Absolute change	7.0 (8)	<.001	(107.7,212.8)
Mean (SD)	957.1(65.8)	160.2(68.4)	20.3(8.8)				
Median	950.0	186.0	23.9	% Change	6.9 (8)	<.001	(13.5, 27.0)
Min; Max	836; 1051	78; 243	9; 31				

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 Grey (10^-6mm2/s)							
Last Observation							
n	9	9	9	Absolute change	7.0 (8)	<.001	(107.7,212.8)
Mean (SD)	957.1(65.8)	160.2(68.4)	20.3(8.8)				
Median	950.0	186.0	23.9	% Change	6.9 (8)	<.001	(13.5, 27.0)
Min; Max	836; 1051	78; 243	9; 31				

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