

Statistical Analyses for Amount of Sleep Measured by Sleep Diary After Hemarthrosis

Statistical analysis title	Amount of Sleep for BeneFIX OD1
Statistical analysis description	Mean difference in duration of sleep on the first night (24 hours post-bleed) and the second night (48 hours post-bleed).
Comparison groups	BeneFIX OD1
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANOVA
Parameter type	Mean difference (net)
Point estimate	0.4
Confidence interval	
level	95%
sides	2-sided
lower limit	0.1
upper limit	0.6

Statistical analysis title	Amount of Sleep for BeneFIX 100 IU/kg
Statistical analysis description	Mean difference in duration of sleep on the first night (24 hours post-bleed) and the second night (48 hours post-bleed).
Comparison groups	BeneFIX 100 IU/kg
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.021
Method	ANOVA
Parameter type	Mean difference (net)
Point estimate	0.4
Confidence interval	
level	95%
sides	2-sided
lower limit	0.1
upper limit	0.8

Statistical analysis title	Amount of Sleep for BeneFIX 50 IU/kg
Statistical analysis description	Mean difference in duration of sleep on the first night (24 hours post-bleed) and the second night (48 hours post-bleed).
Comparison groups	BeneFIX 50 IU/kg
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	ANOVA
Parameter type	Mean difference (net)
Point estimate	0.6
Confidence interval	
level	95%
sides	2-sided
lower limit	0.2
upper limit	0.9

Statistical analysis title	Amount of Sleep for BeneFIX OD2
Statistical analysis description	Mean difference in duration of sleep on the first night (24 hours post-bleed) and the second night (48 hours post-bleed).
Comparison groups	BeneFIX OD2
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.093
Method	ANOVA
Parameter type	Mean difference (net)
Point estimate	0.4
Confidence interval	
level	95%
sides	2-sided
lower limit	-0.1
upper limit	0.8