

Statistical Analyses 1 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 1- Majority reader			Analysis Type	Non-Inferiority			
				Comment	To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%.			
Statistical analysis description	The percentage difference was calculated as gadobutrol-enhanced minus unenhanced MRA. In the below table, "n/n" signifies those subjects/segments that were evaluable for the specified category.							
Comparison groups or subject analysis sets	Gadobutrol-Enhanced MRA versus Unenhanced MRA							
Number of subjects in this analysis	(n=141/158)							
Analysis specification	Pre-specified							
Parameter Estimate								
Parameter type	Other effect estimate: Percentage difference							
Point estimate	5.7							
Confidence interval	Level	Other: 95.1%	Sides	2	Lower limit	-3.6	Upper limit	NA*
Variability estimate	Choose an item.			Dispersion Value				

*NA - Not Appropriate, upper intervals were not used in the statistical analysis and were not of interest for the study.

Statistical Analyses 2 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-Enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 2- Blinded reader 1				Analysis Type	Non-Inferiority				
					Comment	To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%.				
Statistical analysis description	The percentage difference was calculated as gadobutrol-enhanced minus unenhanced MRA. In the below table, "n/n" signifies those subjects/segments that were evaluable for the specified category.									
Comparison groups or subject analysis sets	Gadobutrol-Enhanced MRA versus Unenhanced MRA									
Number of subjects in this analysis	(n=141/158)									
Analysis specification	Pre-specified									
Parameter Estimate										
Parameter type	Other effect estimate: Percentage difference									
Point estimate	5.1									
Confidence interval	Level	Other: 95.1 %			Sides	2	Lower limit	-5.4	Upper limit	NA*
Variability estimate	Choose an item.					Dispersion Value				

*NA - Not Appropriate, upper intervals were not used in the statistical analysis and were not of interest for the study.

Statistical Analyses 3 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-Enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 3 - Blinded reader 2				Analysis Type	Non-Inferiority				
					Comment	To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%.				
Statistical analysis description	The percentage difference was calculated as gadobutrol-enhanced minus unenhanced MRA. In the below table, "n/n" signifies those subjects/segments that were evaluable for the specified category.									
Comparison groups or subject analysis sets	Gadobutrol-Enhanced MRA versus Unenhanced MRA									
Number of subjects in this analysis	(n=141/158)									
Analysis specification	Pre-specified									
Parameter Estimate										
Parameter type	Other effect estimate: Percentage difference									
Point estimate	5.1									
Confidence interval	Level	Other: 95.1%			Sides	2	Lower limit	-4.7	Upper limit	NA*
Variability estimate	Choose an item.				Dispersion Value					

*NA - Not Appropriate, upper intervals were not used in the statistical analysis and were not of interest for the study.

Statistical Analyses 4 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 4 - Blinded reader 3				Analysis Type	Non-Inferiority				
					Comment	To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%.				
Statistical analysis description	The percentage difference was calculated as gadobutrol-enhanced minus unenhanced MRA. In the below table, "n/n" signifies those subjects/segments that were evaluable for the specified category.									
Comparison groups or subject analysis sets	Gadobutrol-Enhanced MRA versus Unenhanced MRA									
Number of subjects in this analysis	(n=141/158)									
Analysis specification	Pre-specified									
Parameter Estimate										
Parameter type	Other effect estimate: Percentage difference									
Point estimate	3.2									
Confidence interval	Level	Other: 95.1%			Sides	2	Lower limit	-5.9	Upper limit	NA*
Variability estimate	Choose an item.					Dispersion Value				

*NA - Not Appropriate, upper intervals were not used in the statistical analysis and were not of interest for the study.

Statistical Analyses 5 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 5 - Clinical investigators				Analysis Type	Non-Inferiority				
					Comment	To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%.				
Statistical analysis description	The percentage difference was calculated as gadobutrol-enhanced minus unenhanced MRA. In the below table, "n/n" signifies those subjects/segments that were evaluable for the specified category.									
Comparison groups or subject analysis sets	Gadobutrol-Enhanced MRA versus Unenhanced MRA									
Number of subjects in this analysis	(n=238/297)									
Analysis specification	Pre-specified									
Parameter Estimate										
Parameter type	Other effect estimate: Percentage difference									
Point estimate	21.5									
Confidence interval	Level	Other: 95.1%			Sides	2	Lower limit	14.1	Upper limit	NA*
Variability estimate	Choose an item.				Dispersion Value					

*NA - Not Appropriate, upper intervals were not used in the statistical analysis and were not of interest for the study.