

Statistical Analyses 1 for Minimum Gadobutrol Performance for Sensitivity: Sensitivity > 50%

Statistical analysis title	Statistical analysis 1- Majority reader			Analysis Type	Other			
				Comment				
Statistical analysis description	Gadobutrol minimum performance criteria was based on a stenosis of 50% calculated from the native vessel diameter. 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							
Number of subjects in this analysis	(n=135/149)							
Analysis specification	Pre-specified							
Parameter Estimate								
Parameter type	Other effect estimate: One sided 95.1% confidence interval							
Point estimate	61.7							
Confidence interval	Level	Other: 95.1%	Sides	1	Lower limit	55.3	Upper limit	
Variability estimate	Choose an item.			Dispersion Value				

Statistical Analyses 2 for Minimum Gadobutrol Performance for Sensitivity: Sensitivity > 50%

Statistical analysis title	Statistical analysis 2- Blinded reader 1				Analysis Type	Other				
					Comment					
Statistical analysis description	Gadobutrol minimum performance criteria was based on a stenosis of 50% calculated from the native vessel diameter. 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									
Number of subjects in this analysis	(n=132/146)									
Analysis specification	Pre-specified									
Parameter Estimate										
Parameter type	Other effect estimate: One sided 95.1% confidence interval									
Point estimate	60.3									
Confidence interval	Level	Other: 95.1 %			Sides	1	Lower limit	53.6	Upper limit	
Variability estimate	Choose an item.				Dispersion Value					

Statistical Analyses 3 for Minimum Gadobutrol Performance for Sensitivity: Sensitivity > 50%

Statistical analysis title	Statistical analysis 3 - Blinded reader 2				Analysis Type	Other				
					Comment					
Statistical analysis description	Gadobutrol minimum performance criteria was based on a stenosis of 50% calculated from the native vessel diameter. 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									
Number of subjects in this analysis	(n=139/156)									
Analysis specification	Pre-specified									
Parameter Estimate										
Parameter type	Other effect estimate: One sided 95.1% confidence interval									
Point estimate	59.6									
Confidence interval	Level	Other: 95.1%			Sides	1	Lower limit	53.1	Upper limit	
Variability estimate	Choose an item.				Dispersion Value					

Statistical Analyses 4 for Minimum Gadobutrol Performance for Sensitivity: Sensitivity > 50%

Statistical analysis title	Statistical analysis 4 - Blinded reader 3			Analysis Type	Other			
				Comment				
Statistical analysis description	Gadobutrol minimum performance criteria was based on a stenosis of 50% calculated from the native vessel diameter. 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							
Number of subjects in this analysis	(n=140/155)							
Analysis specification	Pre-specified							
Parameter Estimate								
Parameter type	Other effect estimate: One sided 95.1% confidence interval							
Point estimate	58.7							
Confidence interval	Level	Other: 95.1%	Sides	1	Lower limit	52.2	Upper limit	
Variability estimate	Choose an item.			Dispersion Value				

Statistical Analyses 5 for Minimum Gadobutrol Performance for Sensitivity: Sensitivity > 50%

Statistical analysis title	Statistical analysis 5 - Clinical investigators				Analysis Type	Other				
					Comment					
Statistical analysis description	Gadobutrol minimum performance criteria was based on a stenosis of 50% calculated from the native vessel diameter. 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									
Number of subjects in this analysis	(n=230 /283)									
Analysis specification	Pre-specified									
Parameter Estimate										
Parameter type	Other effect estimate: One sided 95.1% confidence interval									
Point estimate	61.5									
Confidence interval	Level	Other: 95.1%			Sides	1	Lower limit	56.7	Upper limit	
Variability estimate	Choose an item.				Dispersion Value					