Statistical Analyses 1 for Minimum Gadobutrol Performance for Specificity: Specificity > 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=457/8805)		
Analysis specification	*Pre-specified*		

Parameter Estimate						
Parameter type	Other effect estimate:		One sided 95.1% confidence interval			
Point estimate	98.0					
Confidence interval	Level	Other: 95.1%	Sides	*1*	Lower limit 97.7	Upper limit
Variability estimate	Choose an item.			Dispersion Value		

Statistical Analyses 2 for Minimum Gadobutrol Performance for Specificity: Specificity > 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=444/8225)		
Analysis specification	*Pre-specified*		

Parameter Estimate						
Parameter type	Other effect estimate: One sided 95.1% confidence interval					
Point estimate	97.6					
Confidence interval	Level	Other: 95.1%	Sides	*1*	Lower limit	97.3	Upper limit	
Variability estimate	Choose an item.		Dispersion Value			

Statistical Analyses 3 for Minimum Gadobutrol Performance for Specificity: Specificity > 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=457/8844)		
Analysis specification	*Pre-specified*		
Parameter Estimate			
Parameter type	Other effect estimate: One sided 95.1% confidence interval		
Point estimate	97.2		
Confidence interval	Level	Other: 95.1%	Sides	*1*	Lower limit	96.9	Upper limit	
Variability estimate	Choose an item.			Dispersion Value			

Statistical Analyses 4 for Minimum Gadobutrol Performance for Specificity: Specificity > 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=457/9079)		
Analysis specification	*Pre-specified*		
Parameter Estimate			
Parameter type	Other effect estimate: One sided 95.1% confidence interval		
Point estimate	98.0		

Confidence interval	Level	Other: 95.1%	Sides	*1*	Lower limit	97.7	Upper limit	

Variability estimate	Choose an item.		**Dispersion Value**	

Statistical Analyses 5 for Minimum Gadobutrol Performance for Specificity: Specificity > 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=457/8926)		
Analysis specification	*Pre-specified*		
Parameter Estimate			
Parameter type	Other effect estimate: One sided 95.1% confidence interval		
Point estimate	99.2		

Confidence interval	Level	Other: 95.1%	Sides	*1*	Lower limit	98.9	Upper limit	

Variability estimate	Choose an item.		Dispersion Value	