Statistical Analyses 1 for Percentage of Assessable Vascular Segments Using Gadobutrol-Enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 1- Majority reader	**Analysis Type**	Superiority
		Comment	
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=457/9597)		
Analysis specification	*Pre-specified*		
	Statistical hypothesis test		
P-value	<	Value: 0.0001	**Comment**	
Method **[Required if P-value provided]**	*Other method name: (specify) Cluster adjusted McNemar*		
	Parameter Estimate		
Parameter type	Other effect estimate: Percentage difference		
Point estimate	22.3		

Confidence interval	Level	Other: 95.1%	Sides	2	Lower limit	20.4	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 2 for Percentage of Assessable Vascular Segments Using Gadobutrol-Enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 2- Blinded reader 1	**Analysis Type**	Superiority
		Comment	
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=457/9597)		
Analysis specification	*Pre-specified*		
Statistical hypothesis test			
P-value	<	Value: 0.0001	**Comment**	
Method **[Required if P-value provided]**	*Other method name: (specify) Cluster adjusted McNemar*		
Parameter Estimate			
Parameter type	Other effect estimate: Percentage difference		
Point estimate	63.8		

Confidence interval	Level	Other: 95.1%	Sides	2	Lower limit	60.9	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 3 for Percentage of Assessable Vascular Segments Using Gadobutrol-Enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 3 - Blinded reader 2	**Analysis Type**	Superiority
		Comment	
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=457/9597)		
Analysis specification	*Pre-specified*		
Statistical hypothesis test			
P-value	<	Value: 0.0001	**Comment**
Method **[Required if P-value provided]**	*Other method name: (specify) Cluster adjusted McNemar*		
Parameter Estimate			
Parameter type	Other effect estimate: Percentage difference		
Point estimate	19.6		

Confidence interval	Level	Other: 95.1%	Sides	2	Lower limit	17.8	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 Percentage of Assessable Vascular Segments Using Gadobutrol-Enhanced MRA and Unenhanced MRA

		Analysis Type	Superiority
Statistical analysis title	Statistical analysis 4 - Blinded reader 3	**Comment**	
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=457/9597)		
Analysis specification	*Pre-specified*		
Statistical hypothesis test			
P-value	<	Value: 0.0001	**Comment**	
Method **[Required if P-value provided]**	*Other method name: (specify) Cluster adjusted McNemar*		
Parameter Estimate			
Parameter type	Other effect estimate: Percentage difference		
Point estimate	15.0		

Confidence interval	Level	Other: 95.1%		Sides	2		Lower limit	13.3	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 Percentage of Assessable Vascular Segments Using Gadobutrol-Enhanced MRA and Unenhanced MRA

Statistical analysis title	Statistical analysis 5 - Clinical investigators	**Analysis Type**	Superiority
		Comment	
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=457/9597)		
Analysis specification	*Pre-specified*		
Statistical hypothesis test			
P-value	<	Value: 0.0001	**Comment**
Method **[Required if P-value provided]**	*Other method name: (specify) Cluster adjusted McNemar*		
Parameter Estimate			
Parameter type	Other effect estimate: Percentage difference		
Point estimate	18.5		

Confidence interval	Level	Other: 95.1%	Sides	2	Lower limit	16.5	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.