Statistical Analysis 1 for Presence of a Myocardial Perfusion Defect Indicating Significant CAD per Subject on Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images – Primary Analysis of Sensitivity Comparison Based on the Blinded Readers' Assessment

Statistical analysis title	Statistical analysis 1: Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images	**Analysis Type**	Superiority
		Comment	
Statistical analysis description	Statistical analysis 1 for presence of a myocardial perfusion defect indicating significant CAD per subject on gadobutrol-enhanced CMRI versus unenhanced wall motion CMRI images – primary analysis of sensitivity comparison based on the blinded readers' assessment. Sensitivity of gadobutrol-enhanced CMRI was compared with sensitivity of unenhanced CMRI evaluated by Reader 1.		
Comparison groups or subject analysis sets	Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images		
Number of subjects in this analysis	141		
Analysis specification	*Pre-specified*		
Statistical hypothesis test			
P-value	=	0.8694	**Comment**	
Method **[Required if P-value provided]**	*Other method name: (specify) McNemar 1-sided test,alpha level of 2.5%*		
Parameter Estimate			
Parameter type	Other effect estimate: Sensitivity Difference		
Point estimate	-0.7		

Confidence interval	Level	95%	Sides	*1*	Lower limit	-8.5	Upper limit	-
Variability estimate	Choose an item.				Dispersion Value			

Statistical Analysis 2 for Presence of a Myocardial Perfusion Defect Indicating Significant CAD per Subject on Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images – Primary Analysis of Sensitivity Comparison Based on the Blinded Readers' Assessment

Statistical analysis title	Statistical analysis 2: Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images	**Analysis Type**	Superiority
		Comment	
Statistical analysis description	Statistical analysis 2 for presence of a myocardial perfusion defect indicating significant CAD per subject on gadobutrol-enhanced CMRI versus unenhanced wall motion CMRI images – primary analysis of sensitivity comparison based on the blinded readers' assessment. Sensitivity of gadobutrol-enhanced CMRI was compared with sensitivity of unenhanced CMRI evaluated by Reader 2.		
Comparison groups or subject analysis sets	Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images		
Number of subjects in this analysis	141		
Analysis specification	*Pre-specified*		
Statistical hypothesis test			

P-value	**<**	0.0001	**Comment**	

Method **[Required if P-value provided]**	*Other method name: (specify) McNemar 1-sided test,alpha level of 2.5%*

Parameter Estimate

Parameter type	Other effect estimate: Sensitivity Difference						
Point estimate	29.1						
Confidence interval	Level	95%	Sides	*1*	Lower limit	21.7	Upper limit	-
Variability estimate	Choose an item.		Dispersion Value				

Statistical Analysis 3 for Presence of a Myocardial Perfusion Defect Indicating Significant CAD per Subject on Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images – Primary Analysis of Sensitivity Comparison Based on the Blinded Readers' Assessment

Statistical analysis title	Statistical analysis 3: Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images	**Analysis Type**	Superiority
		Comment	
Statistical analysis description	Statistical analysis 3 for presence of a myocardial perfusion defect indicating significant CAD per subject on gadobutrol-enhanced CMRI versus unenhanced wall motion CMRI images – primary analysis of sensitivity comparison based on the blinded readers' assessment. Sensitivity of gadobutrol-enhanced CMRI was compared with sensitivity of unenhanced CMRI evaluated by Reader 3.		
Comparison groups or subject analysis sets	Gadobutrol-enhanced CMRI Versus Unenhanced Wall Motion CMRI Images		
Number of subjects in this analysis	141		
Analysis specification	*Pre-specified*		
Statistical hypothesis test			

P-value	<	0.0001	**Comment**	

Method **[Required if P-value provided]**	*Other method name: (specify) McNemar 1-sided test,alpha level of 2.5%*

Parameter Estimate

Parameter type	Other effect estimate: Sensitivity Difference					
Point estimate	24.1					
Confidence interval	Level	95%	Sides	*1*	Lower limit	16.6	Upper limit	-
Variability estimate	Choose an item.			Dispersion Value		