

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 – Additional Secondary 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 – additional secondary 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	108							
Analysis specification	<i>Pre-specified</i>							
Statistical hypothesis test								
P-value	=	0.0455	Comment					
Method [Required if P-value provided]	<i>Other method name: (specify) McNemar 1-sided test, alpha level of 2.5%</i>							
Parameter Estimate								
Parameter type	Other effect estimate: Sensitivity Difference							
Point estimate	7.4							
Confidence interval	Level	95%	Sides	1	Lower limit	0.5	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 – Additional Secondary 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 – additional secondary 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	108							
Analysis specification	<i>Pre-specified</i>							
Statistical hypothesis test								
P-value	<	0.0001	Comment					
Method [Required if P-value provided]	<i>Other method name: (specify) McNemar 1-sided test, alpha level of 2.5%</i>							
Parameter Estimate								
Parameter type	Other effect estimate: Sensitivity Difference							
Point estimate	34.3							
Confidence interval	Level	95%	Sides	1	Lower limit	25.2	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 – Additional Secondary 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 – additional secondary 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	108							
Analysis specification	<i>Pre-specified</i>							
Statistical hypothesis test								
P-value	<	0.0001	Comment					
Method [Required if P-value provided]	<i>Other method name: (specify) McNemar 1-sided test, alpha level of 2.5%</i>							
Parameter Estimate								
Parameter type	Other effect estimate: Sensitivity Difference							
Point estimate	30.6							
Confidence interval	Level	95%	Sides	1	Lower limit	21.7	Upper limit	-
Variability estimate	Choose an item.			Dispersion Value				