

Statistical Analysis 1 for Presence of a Myocardial Perfusion Defect Indicating Significant CAD per Subject on Gadobutrol-enhanced CMRI –Secondary Analysis of Sensitivity Based on Investigator's Assessment

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|--|---|-----|--------|---------------|------------------|-------------|------|-------------|------|
| 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 – secondary analysis of sensitivity comparison based on investigator's assessment. Sensitivity of gadobutrol-enhanced CMRI was compared with sensitivity of unenhanced CMRI. Maximum stenosis severity at least >=50% by QCA. | | | | | | | | |
| 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 2-sided test,alpha level of 5% | | | | | | | | |
| Parameter Estimate | | | | | | | | | |
| Parameter type | Other effect estimate: Sensitivity Difference | | | | | | | | |
| Point estimate | 27.9 | | | | | | | | |
| Confidence interval | Level | 95% | | Sides | 2 | Lower limit | 18.5 | Upper limit | 35.8 |
| 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 –Secondary Analysis of Sensitivity Based on Investigator's Assessment

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|--|---|-----|--------|---------------|------------------|--|-------------|------|-------------|------|
| 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 – secondary analysis of sensitivity comparison based on investigator's assessment. Sensitivity of gadobutrol-enhanced CMRI was compared with sensitivity of unenhanced CMRI. Maximum stenosis severity at least >=50% by QCA. | | | | | | | | | |
| 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 2-sided test,alpha level of 10% | | | | | | | | | |
| Parameter Estimate | | | | | | | | | | |
| Parameter type | Other effect estimate: Sensitivity Difference | | | | | | | | | |
| Point estimate | 27.9 | | | | | | | | | |
| Confidence interval | Level | 95% | | Sides | 2 | | Lower limit | 19.9 | Upper limit | 34.4 |
| Variability estimate | Choose an item. | | | | Dispersion Value | | | | | |