

Statistical Analyses 1 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-enhanced MRA and Unenhanced MRA

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|---|---|--------------|--|--|----------------------|--|-------------|------|-------------|-----|
| Statistical analysis title | Statistical analysis 1- Majority reader | | | | Analysis Type | Non-Inferiority | | | | |
| | | | | | Comment | To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%. | | | | |
| 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=141/158) | | | | | | | | | |
| Analysis specification | <i>Pre-specified</i> | | | | | | | | | |
| Parameter Estimate | | | | | | | | | | |
| Parameter type | Other effect estimate: Percentage difference | | | | | | | | | |
| Point estimate | 5.7 | | | | | | | | | |
| Confidence interval | Level | Other: 95.1% | | | Sides | 2 | Lower limit | -3.6 | 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 Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-Enhanced MRA and Unenhanced MRA

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|---|---|---------------|-------|----------------------|--|------|-------------|-----|
| Statistical analysis title | Statistical analysis 2- Blinded reader 1 | | | Analysis Type | Non-Inferiority | | | |
| | | | | Comment | To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%. | | | |
| 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=141/158) | | | | | | | |
| Analysis specification | <i>Pre-specified</i> | | | | | | | |
| Parameter Estimate | | | | | | | | |
| Parameter type | Other effect estimate: Percentage difference | | | | | | | |
| Point estimate | 5.1 | | | | | | | |
| Confidence interval | Level | Other: 95.1 % | Sides | 2 | Lower limit | -5.4 | 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 3 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-Enhanced MRA and Unenhanced MRA

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|---|---|--------------|-------|----------------------|--|------|-------------|-----|
| Statistical analysis title | Statistical analysis 3 - Blinded reader 2 | | | Analysis Type | Non-Inferiority | | | |
| | | | | Comment | To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%. | | | |
| 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=141/158) | | | | | | | |
| Analysis specification | <i>Pre-specified</i> | | | | | | | |
| Parameter Estimate | | | | | | | | |
| Parameter type | Other effect estimate: Percentage difference | | | | | | | |
| Point estimate | 5.1 | | | | | | | |
| Confidence interval | Level | Other: 95.1% | Sides | 2 | Lower limit | -4.7 | 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 Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-enhanced MRA and Unenhanced MRA

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|---|---|--------------|----------------------|--|-------------|------|-------------|-----|
| Statistical analysis title | Statistical analysis 4 - Blinded reader 3 | | Analysis Type | Non-Inferiority | | | | |
| | | | Comment | To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%. | | | | |
| 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=141/158) | | | | | | | |
| Analysis specification | <i>Pre-specified</i> | | | | | | | |
| Parameter Estimate | | | | | | | | |
| Parameter type | Other effect estimate: Percentage difference | | | | | | | |
| Point estimate | 3.2 | | | | | | | |
| Confidence interval | Level | Other: 95.1% | Sides | 2 | Lower limit | -5.9 | 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 5 for Sensitivity for Detection of Clinically Significant Disease Using Gadobutrol-enhanced MRA and Unenhanced MRA

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|---|---|--------------|----------------------|--|-------------|------|-------------|-----|
| Statistical analysis title | Statistical analysis 5 - Clinical investigators | | Analysis Type | Non-Inferiority | | | | |
| | | | Comment | To determine if gadobutrol-enhanced MRA was non-inferior to unenhanced MRA, using a pre-specified non-inferiority margin of -7.5%. | | | | |
| 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=238/297) | | | | | | | |
| Analysis specification | <i>Pre-specified</i> | | | | | | | |
| Parameter Estimate | | | | | | | | |
| Parameter type | Other effect estimate: Percentage difference | | | | | | | |
| Point estimate | 21.5 | | | | | | | |
| Confidence interval | Level | Other: 95.1% | Sides | 2 | Lower limit | 14.1 | 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.