Coronary MDCTA With Iopamidol Injection 370

This study has been completed.

Sponsor:
Bracco Diagnostics, Inc

Information provided by (Responsible Party):
Bracco Diagnostics, Inc

ClinicalTrials.gov Identifier:
NCT00558792

First received: November 13, 2007
Last updated: October 18, 2012
Last verified: October 2012
History of Changes

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Results First Received: August 13, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Diagnostic
Condition:	Coronary Artery Disease
Interventions:	Drug: Isovue 370, 70 mL Drug: Isovue 370, 80 mL Drug: Isovue 370, 90 mL

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Patients were enrolled from December 2007 to December 2009 in 17 investigational sites across the United States of America (USA), 2 investigational sites in Canada and 2 investigational sites in Italy. A blinded read of the images obtained during the study was performed in May 2010.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

This was a Phase II, multicenter, prospective, double-blind, randomized, parallel-group comparison of 3 doses of iopamidol injection 370 when used for coronary MDCTA.

Reporting Groups

	Description
Isovue 370, 70 mL	iopamidol injection 370, 70 mL
Isovue 370, 80 mL	iopamidol injection 370, 80 mL
Isovue 370, 90 mL	iopamidol injection 370, 90 mL

Participant Flow: Overall Study

	Isovue 370, 70 mL	Isovue 370, 80 mL	Isovue 370, 90 mL
STARTED	**68**	**63**	**60**
COMPLETED	**68**	**63**	**60**
NOT COMPLETED	**0**	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	iopamidol injection 370, 70 mL
Isovue 370, 80 mL	iopamidol injection 370, 80 mL
Isovue 370, 90 mL	iopamidol injection 370, 90 mL
Total	Total of all reporting groups

Baseline Measures

	Isovue 370, 70 mL	Isovue 370, 80 mL	Isovue 370, 90 mL	Total
Number of Participants [units: participants]	**68**	**63**	**60**	**191**
Age [units: participants]				
<=18 years	**0**	**0**	**0**	**0**
Between 18 and 65 years	**53**	**49**	**42**	**144**
>=65 years	**15**	**14**	**18**	**47**
Age [units: years] Mean (Standard Deviation)	**57.7 (8.85)**	**57.7 (8.54)**	**58.7 (9.25)**	**58.0 (8.85)**
Gender [units: participants]				
Female	**25**	**27**	**21**	**73**
Male	**43**	**36**	**39**	**118**

Region of Enrollment [units: participants]				
United States	**55**	**50**	**48**	**153**
Canada	**11**	**10**	**10**	**31**
Italy	**2**	**3**	**2**	**7**

Outcome Measures

Hide All Outcome Measures

1. Primary: Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 1 [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 1
Measure Description	For all technically adequate coronary artery segments, each reader was to assess whether each segment was visualized to a quality that was adequate for accurate diagnosis of the presence and severity of stenosis. An adequate quality for the accurate diagnosis of the presence and severity of coronary artery stenosis was comprised of 2 basic features: 1) no more than mild blurring of the spatial distinction between the vessel wall and lumen, and 2) a readily visible distinction in image contrast between calcified plaque, enhanced vessel lumen, and uncalcified vessel wall or plaque.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**68**	**62**	**60**
Number of Segments Present & Technically Adequate Analyzed [units: Segments Present & Technically Adequate]	**963**	**865**	**848**
Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 1 [units: Segments Visualized Accurately]	**949**	**842**	**841**

Statistical Analysis 1 for Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 1

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.0099

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Primary: Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 2 [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 2
Measure Description	For all technically adequate coronary artery segments, each reader was to assess whether each segment was visualized to a quality that was adequate for accurate diagnosis of the presence and severity of stenosis. An adequate quality for the accurate diagnosis of the presence and severity of coronary artery stenosis was comprised of 2 basic features: 1) no more than mild blurring of the spatial distinction between the vessel wall and lumen, and 2) a readily visible distinction in image contrast between calcified plaque, enhanced vessel lumen, and uncalcified vessel wall or plaque.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**

Number of Participants Analyzed [units: participants]	**68**	**62**	**60**
Number of Segments Analyzed [units: Segments]	**1042**	**950**	**927**
Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 2 [units: Segments Visualized Accurately]	**1032**	**924**	**927**

Statistical Analysis 1 for Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 2

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

3. Primary: Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 3 [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 3
Measure Description	For all technically adequate coronary artery segments, each reader was to assess whether each segment was visualized to a quality that was adequate for accurate diagnosis of the presence and severity of stenosis. An adequate quality for the accurate diagnosis of the presence and severity of coronary artery stenosis was comprised of 2 basic features: 1) no more than mild blurring of the spatial distinction between the vessel wall and lumen, and 2) a readily visible distinction in image contrast between calcified plaque, enhanced vessel lumen, and uncalcified vessel wall or plaque.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	

	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	Isovue 370, 80 mL	Isovue 370, 90 mL
Number of Participants Analyzed [units: participants]	**68**	**62**	**60**
Number of Segments Present & Technically Adequate Analyzed [units: Segments Present & Technically Adequate]	**925**	**826**	**817**
Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 3 [units: Segments Visualized Accurately]	**925**	**824**	**817**

Statistical Analysis 1 for Diagnostic Quality of Visualization of Coronary Arteries, Off-Site Reader 3

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.1212

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

4. Primary: Contrast Density (CD) Measurements, Off-Site Reader 1 [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Contrast Density (CD) Measurements, Off-Site Reader 1
Measure Description	For this assessment, each off-site reader was to place regions of interest (ROIs) into the lumens of the mid-portion of the left main coronary artery (LM) (segment number 5), and into the mid-portion of segment number 1 of the right coronary artery (RCA). The mean Hounsfield Units levels and standard deviations (SD) for those 2 ROIs were to be recorded by the reader.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**67**	**58**	**59**
Contrast Density (CD) Measurements, Off-Site Reader 1 [units: Hounsfield Units] Mean (Standard Deviation)	**372.806 (90.5842)**	**398.255 (82.3593)**	**418.197 (97.4072)**

Statistical Analysis 1 for Contrast Density (CD) Measurements, Off-Site Reader 1

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.0200

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

5. Primary: Contrast Density (CD) Measurements, Off-Site Reader 2 [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Contrast Density (CD) Measurements, Off-Site Reader 2
Measure Description	For this assessment, each off-site reader was to place regions of interest (ROIs) into the lumens of the mid-portion of the left main coronary artery (LM) (segment number 5), and into the mid-portion of segment number 1 of the right coronary artery (RCA). The mean Hounsfield Units levels and standard deviations (SD) for those 2 ROIs were to be recorded by the reader.
Time Frame	Immediately post dose

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**67**	**58**	**58**
Contrast Density (CD) Measurements, Off-Site Reader 2 [units: Hounsfield Units] Mean (Standard Deviation)	**364.784 (78.2154)**	**396.291 (85.7038)**	**413.665 (86.0972)**

Statistical Analysis 1 for Contrast Density (CD) Measurements, Off-Site Reader 2

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.0044

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

6. Primary: Contrast Density (CD) Measurements, Off-Site Reader 3 [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Contrast Density (CD) Measurements, Off-Site Reader 3
Measure Description	For this assessment, each off-site reader was to place regions of interest (ROIs) into the lumens of the mid-portion of

	the left main coronary artery (LM) (segment number 5), and into the mid-portion of segment number 1 of the right coronary artery (RCA). The mean Hounsfield Units levels and standard deviations (SD) for those 2 ROIs were to be recorded by the reader.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**64**	**58**	**57**
Contrast Density (CD) Measurements, Off-Site Reader 3 [units: Hounsfield Units] Mean (Standard Deviation)	**363.071 (85.7795)**	**383.841 (96.8142)**	**406.206 (91.9117)**

Statistical Analysis 1 for Contrast Density (CD) Measurements, Off-Site Reader 3

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.0371

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

7. Primary: Validity (Sensitivity and Specificity), Off-Site Reader 1 - Sensitivity [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Validity (Sensitivity and Specificity), Off-Site Reader 1 - Sensitivity
Measure Description	For each technically adequate coronary artery, the readers assessed or excluded the presence of coronary artery stenoses. If more than one stenosis was present in a single vessel, the readers recorded the most significant stenosis. Based on a match or mismatch between computed tomographic angiography (CTA) and coronary angiography as assessed by the adjudicator, each vessel diagnosis by CTA was defined as true negative (TN), false positive (FP), false negative (FN), or true positive (TP) based on coronary angiography findings. Technical inadequacy by multi-detector CTA was counted as FN or FP depending on the diagnostic results from conventional angiography. The percentage (%) of sensitivity [TP/(TP+FN)] is presented.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Number of participants with significant disease (>50% stenosis)

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**65**	**55**	**58**
Number of Vessels Analyzed [units: Vessels]	**257**	**218**	**232**
Validity (Sensitivity and Specificity), Off-Site Reader 1 - Sensitivity [units: Sensitivity (%)]	**63.6**	**65.5**	**77.8**

Statistical Analysis 1 for Validity (Sensitivity and Specificity), Off-Site Reader 1 - Sensitivity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.2758
Difference in Sensitivity between Doses [4]	14.1
95% Confidence Interval	-11.4 to 39.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Validity (Sensitivity and Specificity), Off-Site Reader 1 - Sensitivity

Groups [1]	Isovue 370, 80 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.3102
Difference in Sensitivity between Doses [4]	12.3
95% Confidence Interval	-11.1 to 35.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Validity (Sensitivity and Specificity), Off-Site Reader 1 - Sensitivity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 80 mL
Method [2]	Chi-squared
P Value [3]	0.8893
Difference in Sensitivity between Doses [4]	1.9
95% Confidence Interval	-24.6 to 28.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

8. Primary: Validity (Sensitivity and Specificity), Off-Site Reader 1 - Specificity [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Validity (Sensitivity and Specificity), Off-Site Reader 1 - Specificity
Measure Description	For each technically adequate coronary artery, the readers assessed or excluded the presence of coronary artery stenoses. If more than one stenosis was present in a single vessel, the readers recorded the most significant stenosis. Based on a match or mismatch between computed tomographic angiography (CTA) and coronary angiography as assessed by the adjudicator, each vessel diagnosis by CTA was defined as true negative (TN), false positive (FP), false negative (FN), or true positive (TP) based on coronary angiography findings. Technical inadequacy by multi-detector CTA was counted as FN or FP depending on the diagnostic results from conventional angiography. The percentage (%) of specificity [TN/(TN+FP)] is presented.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Number of participants with significant disease (>50% stenosis)

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**65**	**55**	**58**
Number of Vessels Analyzed [units: Vessels]	**257**	**218**	**232**
Validity (Sensitivity and Specificity), Off-Site Reader 1 - Specificity [units: Specificity (%)]	**98.3**	**95.2**	**96.6**

Statistical Analysis 1 for Validity (Sensitivity and Specificity), Off-Site Reader 1 - Specificity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 90 mL

Method [2]	Chi-squared
P Value [3]	0.2511
Difference in Specificity between Doses [4]	-1.7
95% Confidence Interval	-4.7 to 1.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Validity (Sensitivity and Specificity), Off-Site Reader 1 - Specificity

Groups [1]	Isovue 370, 80 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.4985
Difference in Specificity between Doses [4]	1.3
95% Confidence Interval	-2.6 to 5.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Validity (Sensitivity and Specificity), Off-Site Reader 1 - Specificity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 80 mL
Method [2]	Chi-squared
P Value [3]	0.0693
Difference in Specificity between Doses [4]	-3.1

95% Confidence Interval	-6.5 to 0.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

9. Primary: Validity (Sensitivity and Specificity), Off-Site Reader 2 - Sensitivity [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Validity (Sensitivity and Specificity), Off-Site Reader 2 - Sensitivity
Measure Description	For each technically adequate coronary artery, the readers assessed or excluded the presence of coronary artery stenoses. If more than one stenosis was present in a single vessel, the readers recorded the most significant stenosis. Based on a match or mismatch between computed tomographic angiography (CTA) and coronary angiography as assessed by the adjudicator, each vessel diagnosis by CTA was defined as true negative (TN), false positive (FP), false negative (FN), or true positive (TP) based on coronary angiography findings. Technical inadequacy by multi-detector CTA was counted as FN or FP depending on the diagnostic results from conventional angiography. The percentage (%) of sensitivity [TP/(TP+FN)] is presented.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Number of participants with significant disease (>50% stenosis)

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**65**	**55**	**58**

Number of Vessels Analyzed [units: Vessels]	**257**	**218**	**232**
Validity (Sensitivity and Specificity), Off-Site Reader 2 - Sensitivity [units: Sensitivity (%)]	**68.2**	**79.3**	**66.7**

Statistical Analysis 1 for Validity (Sensitivity and Specificity), Off-Site Reader 2 - Sensitivity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.9104
Difference in Sensitivity between Doses [4]	-1.5
95% Confidence Interval	-27.9 to 24.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Validity (Sensitivity and Specificity), Off-Site Reader 2 - Sensitivity

Groups [1]	Isovue 370, 80 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.2857
Difference in Sensitivity between Doses [4]	-12.6
95% Confidence Interval	-35.7 to 10.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Validity (Sensitivity and Specificity), Off-Site Reader 2 - Sensitivity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 80 mL
Method [2]	Chi-squared
P Value [3]	0.3664
Difference in Sensitivity between Doses [4]	11.1
95% Confidence Interval	-13.3 to 35.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

10. Primary: Validity (Sensitivity and Specificity), Off-Site Reader 2 - Specificity [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Validity (Sensitivity and Specificity), Off-Site Reader 2 - Specificity
Measure Description	For each technically adequate coronary artery, the readers assessed or excluded the presence of coronary artery stenoses. If more than one stenosis was present in a single vessel, the readers recorded the most significant stenosis. Based on a match or mismatch between computed tomographic angiography (CTA) and coronary angiography as assessed by the adjudicator, each vessel diagnosis by CTA was defined as true negative (TN), false positive (FP), false negative (FN), or true positive (TP) based on coronary angiography findings. Technical inadequacy by multi-detector CTA was counted as FN or FP depending on the diagnostic results from conventional angiography. The percentage (%) of specificity [TN/(TN+FP)] is presented.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Number of participants with significant disease (>50% stenosis)

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4

	mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	Isovue 370, 80 mL	Isovue 370, 90 mL
Number of Participants Analyzed [units: participants]	**65**	**55**	**58**
Number of Vessels Analyzed [units: Vessels]	**257**	**218**	**232**
Validity (Sensitivity and Specificity), Off-Site Reader 2 - Specificity [units: Specificity (%)]	**94.5**	**92.1**	**90.7**

Statistical Analysis 1 for Validity (Sensitivity and Specificity), Off-Site Reader 2 - Specificity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.1322
Difference in Specifcity between Doses [4]	-3.7
95% Confidence Interval	-8.7 to 1.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Validity (Sensitivity and Specificity), Off-Site Reader 2 - Specificity

Groups [1]	Isovue 370, 80 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.6381
Difference in Specificity between Doses [4]	-1.3
95% Confidence Interval	-6.9 to 4.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Validity (Sensitivity and Specificity), Off-Site Reader 2 - Specificity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 80 mL
Method [2]	Chi-squared
P Value [3]	0.3217
Difference in Specificity between Doses [4]	-2.4
95% Confidence Interval	-7.2 to 2.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

11. Primary: Validity (Sensitivity and Specificity), Off-Site Reader 3 - Sensitivity [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Validity (Sensitivity and Specificity), Off-Site Reader 3 - Sensitivity
Measure Description	For each technically adequate coronary artery, the readers assessed or excluded the presence of coronary artery stenoses. If more than one stenosis was present in a single vessel, the readers recorded the most significant stenosis. Based on a match or mismatch between computed tomographic angiography (CTA) and coronary angiography as assessed by the adjudicator, each vessel diagnosis by CTA was defined as true negative (TN), false positive (FP), false negative (FN), or true positive (TP) based on coronary angiography findings. Technical inadequacy by multi-detector CTA was counted as FN or FP depending on the diagnostic results from conventional angiography. The percentage (%) of sensitivity [TP/(TP+FN)] is presented.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
Number of participants with significant disease (>50% stenosis)

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**65**	**55**	**58**
Number of Vessels Analyzed [units: Vessels]	**257**	**218**	**232**
Validity (Sensitivity and Specificity), Off-Site Reader 3 - Sensitivity [units: Sensitivity (%)]	**59.1**	**62.1**	**66.7**

Statistical Analysis 1 for Validity (Sensitivity and Specificity), Off-Site Reader 3 - Sensitivity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.5843
Difference in Sensitivity between Doses [4]	7.6
95% Confidence Interval	-19.6 to 34.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Validity (Sensitivity and Specificity), Off-Site Reader 3 - Sensitivity

Groups [1]	Isovue 370, 80 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared

P Value [3]	0.7197
Difference in Sensitivity between Doses [4]	4.6
95% Confidence Interval	-20.5 to 29.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Validity (Sensitivity and Specificity), Off-Site Reader 3 - Sensitivity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 80 mL
Method [2]	Chi-squared
P Value [3]	0.8292
Difference in Sensitivity between Doses [4]	3.0
95% Confidence Interval	-24.1 to 30.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

12. Primary: Validity (Sensitivity and Specificity), Off-Site Reader 3 - Specificity [Time Frame: Immediately post dose]

Measure Type	Primary
Measure Title	Validity (Sensitivity and Specificity), Off-Site Reader 3 - Specificity
Measure Description	For each technically adequate coronary artery, the readers assessed or excluded the presence of coronary artery stenoses. If more than one stenosis was present in a single vessel, the readers recorded the most significant stenosis. Based on a match or mismatch between computed tomographic angiography (CTA) and coronary angiography as

	assessed by the adjudicator, each vessel diagnosis by CTA was defined as true negative (TN), false positive (FP), false negative (FN), or true positive (TP) based on coronary angiography findings. Technical inadequacy by multi-detector CTA was counted as FN or FP depending on the diagnostic results from conventional angiography. The percentage (%) of specificity [TN/(TN+FP)] is presented.
Time Frame	Immediately post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Number of participants with significant disease (>50% stenosis)

Reporting Groups

	Description
Isovue 370, 70 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 milliliters (mL), at a rate of >4 mL per second (/sec), followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 80 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.
Isovue 370, 90 mL	Patients received a randomized total dose of Iopamidol injection 370, which could be 70, 80, or 90 mL, at a rate of >4 mL/sec, followed by a 40 mL saline flush, administered at the same injection rate.

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**65**	**55**	**58**
Number of Vessels Analyzed [units: Vessels]	**257**	**218**	**232**
Validity (Sensitivity and Specificity), Off-Site Reader 3 - Specificity [units: Specificity (%)]	**94.9**	**91.5**	**90.7**

Statistical Analysis 1 for Validity (Sensitivity and Specificity), Off-Site Reader 3 - Specificity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.0888
Difference in Specificity between Doses [4]	-4.2
95% Confidence Interval	-9.0 to 0.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Validity (Sensitivity and Specificity), Off-Site Reader 3 - Specificity

Groups [1]	Isovue 370, 80 mL vs. Isovue 370, 90 mL
Method [2]	Chi-squared
P Value [3]	0.7796
Difference in Specificity between Doses [4]	-0.8
95% Confidence Interval	-6.4 to 4.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Validity (Sensitivity and Specificity), Off-Site Reader 3 - Specificity

Groups [1]	Isovue 370, 70 mL vs. Isovue 370, 80 mL
Method [2]	Chi-squared
P Value [3]	0.1662
Difference in Specificity between Doses [4]	-3.4
95% Confidence Interval	-8.2 to 1.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Study was not powered for diagnostic performance analyses. Sample size was based on quality of visualization of coronary artery segments.
[4]	Other relevant estimation information:
	No text entered.

13. Secondary: Number of Participants Who Experienced Adverse Events With Incidence of 5% or Greater [Time Frame: up to 72 hours post dose]

Measure Type	Secondary
Measure Title	Number of Participants Who Experienced Adverse Events With Incidence of 5% or Greater
Measure Description	Participants who received investigational product (iopamidol injection) and experienced an adverse event (AE). See Adverse Events module for further details.
Time Frame	up to 72 hours post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Isovue 370, 70 mL	iopamidol injection 370, 70 mL
Isovue 370, 80 mL	iopamidol injection 370, 80 mL
Isovue 370, 90 mL	iopamidol injection 370, 90 mL

Measured Values

	Isovue 370, 70 mL	**Isovue 370, 80 mL**	**Isovue 370, 90 mL**
Number of Participants Analyzed [units: participants]	**68**	**63**	**60**
Number of Participants Who Experienced Adverse Events With Incidence of 5% or Greater [units: Participants who Experienced AE(s)]	**15**	**14**	**13**

No statistical analysis provided for Number of Participants Who Experienced Adverse Events With Incidence of 5% or Greater

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Patients were monitored for any untoward medical occurrence from the time they signed the informed consent until 72 hours after the administration of iopamidol injection 370.
Additional Description	Only those adverse events that were reported after the injection of iopamidol injection 370 are presented.

Reporting Groups

	Description

Isovue 370, 70 mL	iopamidol injection 370, 70 mL
Isovue 370, 80 mL	iopamidol injection 370, 80 mL
Isovue 370, 90 mL	iopamidol injection 370, 90 mL

Serious Adverse Events

	Isovue 370, 70 mL	Isovue 370, 80 mL	Isovue 370, 90 mL
Total, serious adverse events			
# participants affected / at risk	**0/68 (0.00%)**	**0/63 (0.00%)**	**0/60 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Patients were monitored for any untoward medical occurrence from the time they signed the informed consent until 72 hours after the administration of iopamidol injection 370.
Additional Description	Only those adverse events that were reported after the injection of iopamidol injection 370 are presented.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Isovue 370, 70 mL	iopamidol injection 370, 70 mL
Isovue 370, 80 mL	iopamidol injection 370, 80 mL
Isovue 370, 90 mL	iopamidol injection 370, 90 mL

Other Adverse Events

	Isovue 370, 70 mL	Isovue 370, 80 mL	Isovue 370, 90 mL
Total, other (not including serious) adverse events			
# participants affected / at risk	**15/68 (22.06%)**	**14/63 (22.22%)**	**13/60 (21.67%)**
General disorders			
Feeling Hot † 1			
# participants affected / at risk	**6/68 (8.82%)**	**5/63 (7.94%)**	**5/60 (8.33%)**
# events	**6**	**5**	**5**
Injection Site Erythema † 1			
# participants affected / at risk	**0/68 (0.00%)**	**5/63 (7.94%)**	**1/60 (1.67%)**
# events	**0**	**5**	**1**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**7/68 (10.29%)**	**6/63 (9.52%)**	**2/60 (3.33%)**
# events	**7**	**6**	**2**
Vascular disorders			
Flushing † 1			

# participants affected / at risk	4/68 (5.88%)	4/63 (6.35%)	5/60 (8.33%)
# events	4	4	5

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA version 12.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The results of the study may be presented during scientific symposia or published in a scientific journal only after review by Bracco in accordance with the guidelines set forth in the applicable publication or financial agreement.

Results Point of Contact:

Name/Title: Usha Halemane, Executive Director of Medical Biometrics and Medical Writing
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e-mail: usha.halemane@diag.bracco.com

No publications provided

Responsible Party:	Bracco Diagnostics, Inc
ClinicalTrials.gov Identifier:	NCT00558792 History of Changes
Other Study ID Numbers:	**IOP 108**
Study First Received:	November 13, 2007
Results First Received:	August 13, 2012
Last Updated:	October 18, 2012
Health Authority:	United States: Food and Drug Administration

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For Patients and Families | For Researchers | For Study Record Managers

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