Kidney Damage in Patients With Normal eGFR

This study has been completed.

Sponsor:
Bracco Diagnostics, Inc

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

ClinicalTrials.gov Identifier:
NCT01137786

First received: June 3, 2010
Last updated: August 7, 2013
Last verified: April 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: May 22, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Diagnostic
Condition:	Coronary Artery Stenosis
Intervention:	Drug: Non ionic contrast media comparator

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
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Iodixanol 320	Non ionic contrast media comparator : one time administration for PCI

Iopamidol 370	Non ionic contrast media comparator : one time administration for PCI

Participant Flow: Overall Study

	Iodixanol 320	Iopamidol 370
STARTED	25	24
COMPLETED	24	21
NOT COMPLETED	1	3
Lost to Follow-up	0	2
Withdrawal by Subject	1	1

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.
Evaluable patient population for NGAL analysis included all patients with both pre-dose baseline and post-dose blood and/or urine NGAL values for at least 2 out of the 4 planned measurements within 24 hours post-administration.

Reporting Groups

	Description
Iodixanol 320 NGAL Evaluable Population	Non-ionic contrast media comparator: one time administration for PCI
Iopamidol 370 NGAL Evaluable Population	Non-ionic contrast media comparator: one time administration for PCI
Total	Total of all reporting groups

Baseline Measures

	Iodixanol 320 NGAL Evaluable Population	Iopamidol 370 NGAL Evaluable Population	Total
Number of Participants [units: participants]	21	21	42
Age [units: participants]			
<=18 years	0	0	0
Between 18 and 65 years	11	10	21
>=65 years	10	11	21
Age [units: years] Mean (Standard Deviation)	62.0 (10.65)	63.4 (12.82)	62.7 (11.66)
Gender [units: participants]			
Female	4	5	9
Male	17	16	33
Region of Enrollment [units: participants]			

United States	**17**	**16**	**33**
Italy	**4**	**5**	**9**

Outcome Measures

1. Primary: Impact on the Trajectory of Serum and Urinary NGAL Following the Administration of Non-ionic Low Osmolar Contrast Media. [Time Frame: Baseline and 2, 4, 6, 24, 48, and 72 hours post-dose]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Impact on the Trajectory of Serum and Urinary NGAL Following the Administration of Non-ionic Low Osmolar Contrast Media.
Measure Description	Mean change from baseline values for serum NGAL at 2,4,6,24,48 and 72 hours, and urine NGAL at 2,4,6,24, and 48 hours following the administration of non-ionic low osmolar contrast media.
Time Frame	Baseline and 2, 4, 6, 24, 48, and 72 hours post-dose
Safety Issue	Yes

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
Iodixanol 320 Serum NGAL	Serum NGAL (ng/mL) mean change from baseline at 2,4,6,24,48, and 72 hours post-administration of iodixanol 320.
Iodixanol 320 Urine NGAL	Urine NGAL (ng/mL) mean change from baseline at 2,4,6,24, and 48 hours post-administration of iodixanol 320.
Iopamidol 370 Serum NGAL	Serum NGAL (ng/mL) mean change from baseline at 2,4,6,24,48, and 72 hours post-administration of iopamidol 370.
Iopamidol 370 Urine NGAL	Urine NGAL (ng/mL) mean change from baseline at 2,4,6,24, and 48 hours post-administration of iopamidol 370.

Measured Values

	Iodixanol 320 Serum NGAL	**Iodixanol 320 Urine NGAL**	**Iopamidol 370 Serum NGAL**	**Iopamidol 370 Urine NGAL**
Number of Participants Analyzed [units: participants]	**21**	**21**	**21**	**21**
Impact on the Trajectory of Serum and Urinary NGAL Following the Administration of Non-ionic Low Osmolar Contrast Media. [units: ng/mL] Mean (Standard Deviation)				
2 hours post-dose	**-14.84 (35.46)**	**-17.71 (49.04)**	**-9.98 (22.80)**	**-2.37 (5.45)**
4 hours post-dose	**-12.86 (30.57)**	**-29.33 (64.65)**	**-5.93 (26.62)**	**-2.70 (7.09)**

6 hours post-dose	-16.36 (28.77)	-17.90 (51.38)	-5.60 (24.50)	-2.29 (7.66)
24 hours post-dose	28.35 (39.21)	-2.10 (46.94)	20.15 (32.74)	2.31 (8.70)
48 hours post-dose	18.76 (62.77)	-14.60 (34.69)	34.03 (46.27)	7.37 (22.84)
72 hours post-dose	18.34 (52.28)	NA [1]	26.59 (48.13)	NA [1]

[1] Urine NGAL not measured at this time point as per protocol.

No statistical analysis provided for Impact on the Trajectory of Serum and Urinary NGAL Following the Administration of Non-ionic Low Osmolar Contrast Media.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Iodixanol 320	Non ionic contrast media comparator : one time administration for PCI
Iopamidol 370	Non ionic contrast media comparator : One time administration for PCI

Serious Adverse Events

	Iodixanol 320	Iopamidol 370
Total, serious adverse events		
# participants affected / at risk	**1/25 (4.00%)**	**0/24 (0.00%)**
Cardiac disorders		
Ventricular Fibrillation		
# participants affected / at risk	**1/25 (4.00%)**	**0/24 (0.00%)**
# events	**1**	**0**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Iodixanol 320	Non ionic contrast media comparator : one time administration for PCI
Iopamidol 370	Non ionic contrast media comparator : One time administration for PCI

Other Adverse Events

	Iodixanol 320	Iopamidol 370
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/25 (0.00%)**	**0/24 (0.00%)**

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.

Results Point of Contact:

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No publications provided

Responsible Party: Bracco Diagnostics, Inc
ClinicalTrials.gov Identifier: NCT01137786 History of Changes
Other Study ID Numbers: **IOP-116**

Study First Received:	June 3, 2010
Results First Received:	May 22, 2013
Last Updated:	August 7, 2013
Health Authority:	Italy: Ethics Committee United States: Institutional Review Board

TO TOP

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

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