Trial record **1 of 1** for: 2007-000713-11
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A Study to Evaluate the Discontinuation Effect of Clopidogrel After Drug Eluting Stent Implantation in Non-diabetic Patients (DECADES)

This study has been completed.

Sponsor:
Bristol-Myers Squibb

Collaborator:
Sanofi

Information provided by:
Bristol-Myers Squibb

ClinicalTrials.gov Identifier:
NCT00493779

First received: June 27, 2007
Last updated: August 3, 2010
Last verified: June 2010
History of Changes

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

Purpose

The purpose of the study is to look at the biomarkers of inflammation and platelet activation in patients with drug eluting stents implanted approximately 12 months ago on aspirin and statin, for a 4-week period after the routine discontinuation of clopidogrel

Condition	Intervention	Phase
Antiplatelet Aggregation	Procedure: Blood Collection	Phase 4

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label

Official Title: An Exploratory, Multi-Center, Open-Label, Single-Arm Study to Evaluate the Discontinuation Effect of Clopidogrel After Drug Eluting Stent (DECADES) on Inflammatory and Platelet Activation Markers in Subjects Who Are Receiving Low Dose Acetylsalicylic Acid (ASA)

Resource links provided by NLM:

Drug Information available for: Clopidogrel bisulfate

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Adjusted Mean Percent Changes From Baseline in Soluble CD40 Ligand (sCD40L) [Time Frame: Week 1, Week 2, Week 3, Week 4 (primary timepoint)] [Designated as safety issue: No]

  Based on ANCOVA models performed on log scale controlling for site & natural logarithm of baseline soluble CD40 Ligand value. Percent changes from baseline can be interpreted as the difference of biomarker timepoint value minus baseline value divided by baseline value. Positive percent change might indicate possible enhanced platelet activation.

Secondary Outcome Measures:

- Adjusted Mean Percent Changes From Baseline in Plasma Soluble P-Selectin [Time Frame: Week 1, Week 2, Week 3, Week 4] [Designated as safety issue: No]

  Based on ANCOVA models performed on log scale controlling for site and natural logarithm of baseline Plasma Soluble P-selectin value. Percent changes from baseline can be interpreted as difference of biomarker timepoint value minus baseline value divided by baseline value. Positive percent change is known to be mediated by increases in sCD40L.

- Adjusted Mean Percent Changes From Baseline in Hs-CRP [Time Frame: Week 1, Week 2, Week 3, Week 4] [Designated as safety issue: No]

ANCOVA models performed on log scale controlling for site & natural logarithm of baseline hs-CRP. Back-transformed mean percent changes are presented. Percent changes from baseline can be interpreted as difference of biomarker timepoint value - baseline value ÷ baseline value. Since there is no measure of platelet inhibition or overall thrombogenicity assay presented here, a negative percent change for this measure can not be judged on its own as indicating improvement.

- Adverse Events (AE) / Serious Adverse Events (SAE)Deaths, and AEs Leading to Discontinuation of Follow-up [Time Frame: Throughout 4-week follow-up period] [Designated as safety issue: Yes]

  An AE is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a patient or clinical investigation subject administered an investigational (medicinal) product and that does not necessarily have a causal relationship with this treatment. An SAE is any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is an important medical event.

Enrollment: 103
Study Start Date: October 2007
Study Completion Date: June 2008
Primary Completion Date: June 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
No Intervention: 1 Effect of Clopidogrel withdrawal on biomarkers will be assessed via blood draws	Procedure: Blood Collection 4 weeks

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Subjects with one or more drug-eluting stents of any type who are coming to the end of their 12 months of clopidogrel (75 mg daily) treatment
- Subjects receiving low dose ASA
- Subjects receiving a statin
- Current medication regimen (including ASA and statins) must have been stable for three (3) months. i.e. no initiation of new prescription medication or change in dosage of any previously initiated medication within three (3) months of entering this study
- Subjects with no clinical history of diabetes mellitis
- Men and women, ages 18 years or older

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00493779

Locations

France

Local Institution
Paris, France, 75013

Germany

Local Institution
Mainz, Germany, 55101

Netherlands

Local Institution
Nieuwegein, Netherlands, 3435 CM

Local Institution
Rotterdam, Netherlands, 3015 GD

United Kingdom

Local Institution
Glasgow, Central, United Kingdom, G11 6NT

Local Institution

Southampton, Hampshire, United Kingdom, SO16 6YD

Sponsors and Collaborators

Bristol-Myers Squibb

Sanofi

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Additional Information:

BMS Clinical Trials Disclosure

For FDA Safety Alerts and Recalls refer to the following link: http://www.fda.gov/MEDWATCH/safety.htm

Publications:

Wykrzykowska JJ, Warnholtz A, de Jaeger P, Curzen N, Oldroyd KG, Collet JP, Ten Berg JM, Rademaker T, Goedhart D, Lissens J, Kint PP, Serruys PW. Effect of clopidogrel discontinuation at 1 year after drug eluting stent placement on soluble CD40L, P-selectin and C-reactive protein levels: DECADES (Discontinuation Effect of Clopidogrel After Drug Eluting Stent): a multicenter, open-label study. J Thromb Thrombolysis. 2009 Nov;28(4):410-7. doi: 10.1007/s11239-009-0354-y.

Responsible Party:	Study Director, Bristol-Myers Squibb
ClinicalTrials.gov Identifier:	NCT00493779 History of Changes
Other Study ID Numbers:	CV149-208 Eudract number: **2007-000713-11**
Study First Received:	June 27, 2007
Results First Received:	June 5, 2009
Last Updated:	August 3, 2010
Health Authority:	France: Agence du Medicament (Drug Agency)

Additional relevant MeSH terms:

Clopidogrel	Purinergic Agents
Platelet Aggregation Inhibitors	Neurotransmitter Agents
Purinergic P2Y Receptor Antagonists	Molecular Mechanisms of Pharmacological Action
Purinergic P2 Receptor Antagonists	Physiological Effects of Drugs
Purinergic Antagonists	

ClinicalTrials.gov processed this record on August 04, 2016

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

Results First Received: June 5, 2009

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label
Condition:	Antiplatelet Aggregation
Intervention:	Procedure: Blood Collection

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
103 subjects who were enrolled and treated with clopidogrel, were enrolled, of which 98 subjects had discontinued clopidogrel treatment and entered follow-up phase (study phase).

Reporting Groups

	Description
Clopidogrel Withdrawal Population	All enrolled participants in whom clopidogrel treatment was discontinued.

Participant Flow: Overall Study

	Clopidogrel Withdrawal Population
STARTED	98 [1]
COMPLETED	97 [2]
NOT COMPLETED	1
Logistical issue at site	1

[1] Number of subjects who had discontinued clopidogrel treatment and entered follow-up phase
[2] Completed follow-up phase

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
Clopidogrel Withdrawal Population	All enrolled participants in whom clopidogrel treatment was discontinued.

Baseline Measures

	Clopidogrel Withdrawal Population
Number of Participants [units: participants]	98
Age [units: years] Mean (Standard Deviation)	63.3 (8.5)
Age [units: years] Median (Full Range)	63 (44 to 81)
Gender [units: participants]	
Female	20
Male	78
Race/Ethnicity, Customized [units: participants]	
Caucasian	93
Asian Oriental	5
Mean Baseline High Sensitivity C-Reactive Protein (hs-CRP) [units: mg/L] Mean (Standard Deviation)	1.70 (2.052)
Mean Baseline Plasma Soluble P-Selectin [units: ng/mL] Mean (Standard Deviation)	44.59 (14.898)
Mean Baseline Soluble CD40 Ligand [units: ng/L] Mean (Standard Deviation)	223.76 (186.513)

Outcome Measures

Hide All Outcome Measures

1. Primary: Adjusted Mean Percent Changes From Baseline in Soluble CD40 Ligand (sCD40L) [Time Frame: Week 1, Week 2, Week 3, Week 4 (primary timepoint)]

Measure Type	Primary
Measure Title	Adjusted Mean Percent Changes From Baseline in Soluble CD40 Ligand (sCD40L)
Measure Description	Based on ANCOVA models performed on log scale controlling for site & natural logarithm of baseline soluble CD40 Ligand value. Percent changes from baseline can be interpreted as the difference of biomarker timepoint value minus baseline value divided by baseline value. Positive percent change might indicate possible enhanced platelet activation.
Time Frame	Week 1, Week 2, Week 3, Week 4 (primary timepoint)
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 in the biomarker analysis population having a baseline soluble CD40 Ligand value (n=95) and at least one post-clopidogrel withdrawal measurement for soluble CD40 Ligand value. No imputation technique for missing values was applied.

Reporting Groups

	Description
Biomarker Analysis Population	All participants in the Clopidogrel Withdrawal Population having a baseline and at least one post clopidogrel withdrawal measurement for any of the 3 biomarkers collected.

Measured Values

	Biomarker Analysis Population
Number of Participants Analyzed [units: participants]	**95**
Adjusted Mean Percent Changes From Baseline in Soluble CD40 Ligand (sCD40L) [units: percent change] Mean (Standard Error)	
Baseline value (units=ng/L) (n=95)	**223.76 (19.14)**
Mean Percent Change from Baseline at Week 1 (n=92)	**35.04 (10.37)**
Mean Percent Change from Baseline at Week 2 (n=91)	**38.88 (10.76)**
Mean Percent Change from Baseline at Week 3 (n=91)	**32.74 (9.68)**
Mean Percent Change from Baseline at Week 4 (n=89)	**39.42 (11.07)**

No statistical analysis provided for Adjusted Mean Percent Changes From Baseline in Soluble CD40 Ligand (sCD40L)

2. Secondary: Adjusted Mean Percent Changes From Baseline in Plasma Soluble P-Selectin [Time Frame: Week 1, Week 2, Week 3, Week 4]

Measure Type	Secondary
Measure Title	Adjusted Mean Percent Changes From Baseline in Plasma Soluble P-Selectin
Measure Description	Based on ANCOVA models performed on log scale controlling for site and natural logarithm of baseline Plasma Soluble P-selectin value. Percent changes from baseline can be interpreted as difference of biomarker timepoint value minus baseline value divided by baseline value. Positive percent change is known to be mediated by increases in sCD40L.
Time Frame	Week 1, Week 2, Week 3, Week 4
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 patients in the biomarker analysis population having baseline Plasma Soluble P-selectin value (n=95) and at least one post-clopidogrel withdrawal measurement for Plasma Soluble P-selectin value. No imputation technique for missing values was applied.

Reporting Groups

	Description
Biomarker Analysis Population	All participants in the Clopidogrel Withdrawal Population having a baseline and at least one post clopidogrel withdrawal measurement for any of the 3 biomarkers collected.

Measured Values

	Biomarker Analysis Population
Number of Participants Analyzed [units: participants]	**95**
Adjusted Mean Percent Changes From Baseline in Plasma Soluble P-Selectin [units: percent change] Mean (Standard Error)	
Baseline Value (units=ng/mL) (n=95)	**44.59 (1.53)**

Mean Percent Change from Baseline at Week 1 (n=92)	**9.00 (2.38)**
Mean Percent Change from Baseline at Week 2 (n=91)	**11.10 (2.11)**
Mean Percent Change from Baseline at Week 3 (n=91)	**3.63 (2.69)**
Mean Percent Change from Baseline at Week 4 (n=89)	**1.90 (2.76)**

No statistical analysis provided for Adjusted Mean Percent Changes From Baseline in Plasma Soluble P-Selectin

3. Secondary: Adjusted Mean Percent Changes From Baseline in Hs-CRP [Time Frame: Week 1, Week 2, Week 3, Week 4]

Measure Type	Secondary
Measure Title	Adjusted Mean Percent Changes From Baseline in Hs-CRP
Measure Description	ANCOVA models performed on log scale controlling for site & natural logarithm of baseline hs-CRP. Back-transformed mean percent changes are presented. Percent changes from baseline can be interpreted as difference of biomarker timepoint value - baseline value ÷ baseline value. Since there is no measure of platelet inhibition or overall thrombogenicity assay presented here, a negative percent change for this measure can not be judged on its own as indicating improvement.
Time Frame	Week 1, Week 2, Week 3, Week 4
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 patients in the biomarker analysis population having baseline hs-CRP value and at least one post clopidogrel withdrawal measurement for hs-CRP value. No imputation technique for missing values was applied.

Reporting Groups

	Description
Biomarker Analysis Population	All participants in the Clopidogrel Withdrawal Population having a baseline and at least one post clopidogrel withdrawal measurement for any of the 3 biomarkers collected.

Measured Values

	Biomarker Analysis Population
Number of Participants Analyzed [units: participants]	**98**
Adjusted Mean Percent Changes From Baseline in Hs-CRP [units: percent change] Mean (Standard Error)	
Baseline Value (units=mg/L) (n=98)	**1.70 (0.21)**
Mean Percent Change from Baseline at Week 1 (n=97)	**-20.59 (6.76)**
Mean Percent Change from Baseline at Week 2 (n=95)	**-22.89 (6.78)**
Mean Percent Change from Baseline at Week 3 (n=96)	**-19.32 (8.22)**
Mean Percent Change from Baseline at Week 4 (n=96)	**-17.70 (8.48)**

No statistical analysis provided for Adjusted Mean Percent Changes From Baseline in Hs-CRP

4. Secondary: Adverse Events (AE) / Serious Adverse Events (SAE)Deaths, and AEs Leading to Discontinuation of Follow-up [Time Frame: Throughout 4-week follow-up period]

Measure Type	Secondary
Measure Title	Adverse Events (AE) / Serious Adverse Events (SAE)Deaths, and AEs Leading to Discontinuation of Follow-up
Measure Description	An AE is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a patient or clinical investigation subject administered an investigational (medicinal) product and that does not necessarily have a causal relationship with this treatment. An SAE is any untoward medical occurrence that at any dose results in death, is

	life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is an important medical event.
Time Frame	Throughout 4-week follow-up period
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.
All enrolled patients in whom clopidogrel treatment was discontinued.

Reporting Groups

	Description
Clopidogrel Withdrawal Population	All enrolled participants in whom clopidogrel treatment was discontinued.

Measured Values

	Clopidogrel Withdrawal Population
Number of Participants Analyzed [units: participants]	**98**
Adverse Events (AE) / Serious Adverse Events (SAE)Deaths, and AEs Leading to Discontinuation of Follow-up [units: Participants]	
Deaths	**0**
Any AE	**20**
AEs leading up to Discontinuation	**0**
SAEs	**2**

No statistical analysis provided for Adverse Events (AE) / Serious Adverse Events (SAE)Deaths, and AEs Leading to Discontinuation of Follow-up

▶ Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Clopidogrel Withdrawal Population	All enrolled participants in whom clopidogrel treatment was discontinued.

Serious Adverse Events

	Clopidogrel Withdrawal Population
Total, serious adverse events	
# participants affected / at risk	**2/98 (2.04%)**
Cardiac disorders	
Angina unstable * 1	
# participants affected / at risk	**1/98 (1.02%)**
General disorders	
Non-cardiac chest pain * 1	
# participants affected / at risk	**1/98 (1.02%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 10.0

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
Clopidogrel Withdrawal Population	All enrolled participants in whom clopidogrel treatment was discontinued.

Other Adverse Events

	Clopidogrel Withdrawal Population
Total, other (not including serious) adverse events	
# participants affected / at risk	**0/98 (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
The open-label and exploratory nature of this small study and the absence of control group inherently limit the interpretability of the results.

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:** Bristol-Myers Squibb Co. agreements with investigators vary; constant is our right to embargo communications regarding trial results prior to public release for a period ≤60 days from submittal for review. We will not prohibit investigators from publishing, but will prohibit the disclosure of previously undisclosed confidential information other than study results, and request postponement of single-center publications until after disclosure of the clinical trial's primary publication.

Results Point of Contact:

Name/Title: BMS Study Director
Organization: Bristol-Myers Squibb
e-mail: Clinical.Trials@bms.com

Publications:

Wykrzykowska JJ, Warnholtz A, de Jaeger P, Curzen N, Oldroyd KG, Collet JP, Ten Berg JM, Rademaker T, Goedhart D, Lissens J, Kint PP, Serruys PW. Effect of clopidogrel discontinuation at 1 year after drug eluting stent placement on soluble CD40L, P-selectin and C-reactive protein levels: DECADES (Discontinuation Effect of Clopidogrel After Drug Eluting Stent): a multicenter, open-label study. J Thromb Thrombolysis. 2009 Nov;28(4):410-7. doi: 10.1007/s11239-009-0354-y.

Responsible Party:	Study Director, Bristol-Myers Squibb
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Health Authority:	France: Agence du Medicament (Drug Agency)