Protocol Registration Receipt
06/14/2012

Grantor: CDER IND/IDE Number: 51,126 Serial Number:

# Fondaparinux Trial With Unfractionated Heparin (UFH) During Revascularization in Acute Coronary Syndromes (ACS) (FUTURA/OASIS 8)

This study has been completed.

| | |
|---|---|
| Sponsor: | GlaxoSmithKline |
| Collaborators: | |
| Information provided by (Responsible Party): | GlaxoSmithKline |
| ClinicalTrials.gov Identifier: | NCT00790907 |

## Purpose

The purpose of this study is to compare the safety of two different dose regimens of unfractionated heparin (UFH) during a percutaneous coronary intervention (PCI) procedure in patients with UA (unstable angina)/NSTEMI (non ST segment elevation myocardial infarction) who have been initially treated with fondaparinux.

| Condition | Intervention | Phase |
|---|---|---|
| Unstable Angina<br>Non ST Segment Elevation Myocardial Infarction | Drug: fondaparinux background and standard dose UFH<br>Drug: Fondaparinux background and low dose heparin<br>Drug: Open label fondaparinux | Phase 4 |

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Safety Study
Official Title: FondaparinUx Trial With Unfractionated Heparin (UFH) During Revascularization in Acute Coronary Syndromes (ACS) (FUTURA). A Prospective Study Evaluating the Safety of Two Regimens of Adjunctive Intravenous UFH During PCI in High Risk Patients With Unstable Angina/Non ST Segment Elevation Myocardial Infarction (UA/NSTEMI) Initially Treated With Subcutaneous Fondaparinux and Referred for Early Coronary Angiography (OASIS 8)

## Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Number of Participants With Composite of Major Bleeding, Minor Bleeding, or Major Vascular Access Site Complications During the Peri-PCI Period [Time Frame: Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total)] [Designated as safety issue: Yes]

  The peri-percutaneous coronary intervention (peri-PCI) period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Major and minor bleeding events were adjudicated by a blinded central independent adjudication committee (CIAC). Major vascular access site complications comprised large hematoma, pseudoaneurysm requiring treatment, aterio-venous fistula, or other vascular procedures related to the access site.

Secondary Outcome Measures:

- Number of Participants With Composite of Major Bleeding During the Peri-PCI Period, With Death, MI, or TVR at Day 30 [Time Frame: Peri-PCI period for major bleeding (during the time from randomization up to 48 hours after the end of PCI [typically 49 hours total] ) and from randomization up to Day 30 for death, MI, or TVR] [Designated as safety issue: Yes]

  The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Assessment of death, myocardial infarction (MI) and target vessel revascularisation (TVR) was performed at Day 30. Major bleeding, MI and TVR were adjudicated by a blinded CIAC.
- Number of Participants With Major Bleeding During the Peri-PCI Period [Time Frame: Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total)] [Designated as safety issue: Yes]

  The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Major bleeding, MI and TVR were adjudicated by a blinded CIAC.

- Number of Participants With Minor Bleeding During the Peri-PCI Period [Time Frame: Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total)] [Designated as safety issue: Yes]
  The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Minor bleeding events were adjudicated by a blinded CIAC.
- Number of Participants With Major Vascular Access Site Complications During the Peri-PCI Period [Time Frame: Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total)] [Designated as safety issue: Yes]
  The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Major vascular access site complications included: large hematoma, pseudoaneurysm requiring treatment, arterio-venous fistula, or other vascular procedures related to the access site.
- Number of Participants With Major PCI-related Procedural Complications [Time Frame: During PCI procedure: immediately after randomization (approximately 10-75 minutes)] [Designated as safety issue: Yes]
  Major PCI-related procedural complications included: abrupt vessel closure, a new angiographic filling defect representing either angiographic thrombus or major dissection with reduced flow, no-reflow phenomenon, or catheter-related thrombus. Investigator reports of catheter-related thrombus were defined as suspected catheter-related thrombus events, and were adjudicated by a blinded CIAC.
- Number of Participants With Composite of Death, MI or TVR During the Peri-PCI Period and at Day 30 [Time Frame: Peri-PCI (during the time from randomization up to 48 hours after the end of PCI, typically 49 hours total) and from randomization up to Day 30] [Designated as safety issue: Yes]
  The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Assessment of composite of death, MI, or TVR was performed both during the peri-PCI period and at Day 30. MI and TVR events were adjudicated by a blinded CIAC.
- Number of Participants Experiencing Death, MI, TVR, Definite/Probable Stent Thrombosis, or Stroke, Assessed Separately During the Peri-PCI Period and at Day 30 [Time Frame: Peri-PCI (during the time from randomization up to 48 hours after the end of PCI, typically 49 hours total) and from randomization up to Day 30] [Designated as safety issue: Yes]
  The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Assessment of death, MI, TVR, definite/probable stent thrombosis, or stroke was performed during the peri-PCI period and at Day 30. MI, TVR, definite/probable stent thrombosis, and stroke events were adjudicated by a blinded CIAC.

Enrollment: 3235
Study Start Date: February 2009
Study Completion Date: May 2010
Primary Completion Date: May 2010

| Arms | Assigned Interventions |
|---|---|
| Experimental: Open label fondaparinux background and standard dose UFH | Drug: fondaparinux background and standard dose UFH<br>Open label fondaparinux syringes pre-filled with 2.5 |

| Arms | Assigned Interventions |
| --- | --- |
| Subjects indicated for PCI and randomized to receive standard dose UFH | mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned glycoprotein [GP] IIb/IIIa inhibitor use: 60 units/kilogram (U/kg); no planned use: 85 U/kg and adjusted based on activated clotting time (ACT) [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |
| Experimental: Open label fondaparinux background and low dose UFH<br>Subjects indicated for PCI and randomized to receive low dose UFH | Drug: Fondaparinux background and low dose heparin<br>Open label fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose UFH (50 U/kg), which was not adjusted for planned GPIIb/IIIa inhibitor use or ACT). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |
| Open label fondapaparinux<br>Subjects not indicated for PCI and not randomized | Drug: Open label fondaparinux<br>Open-label fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier, for those participants not indicated for PCI and not randomized |

Subjects presenting at hospital with suspected UA or NSTEMI and who are likely to undergo angiography (ideally within 72 hours) will be assessed for eligibility and consented. Suitable subjects will be enrolled and commence treatment with open-label fondaparinux, 2.5 milligram (mg), subcutaneous (s.c.), once daily. Following angiography subjects indicated for PCI and meeting the additional requirements for randomization will be randomised to receive one of two dose regimens of UFH either standard dose or low dose immediately prior to the PCI procedure. Post-PCI, therapy with fondaparinux (2.5 mg, s.c.) may be resumed at the investigator's discretion for up to a maximum of 8 days or hospital discharge, whichever is earlier.

Subjects not indicated for PCI, will continue treatment with fondaparinux, 2.5mg, s.c, once daily for up to 8 days or hospital discharge, whichever is earlier.

All subjects will be followed up for 30 days after randomization/angiography.

## Eligibility

Ages Eligible for Study: 21 Years and older
Genders Eligible for Study: Both

The following are inclusion and exclusion criteria for enrollment in the study:

Inclusion Criteria:

- Presenting or admitted to hospital with symptoms suspected to represent UA or NSTEMI, i.e., clinical history consistent with new onset, or a worsening pattern of, characteristic ischemic chest pain or ischemic symptoms occurring at rest or with minimal activity (lasting longer than 5 minutes or requiring sublingual nitro-glycerine for relief of the pain).
- Available to be enrolled within 48 hours of the onset of the most recent episode of symptoms.
- Planned coronary angiography, with PCI if indicated, within 72 hours of enrollment where possible.
- At least two of the three following additional criteria:
- Age greater than or equal to 60 years
- Troponin T or I or CK-MB above the upper limit of normal for the local institution;
- Electrocardiogram (ECG) changes compatible with ischemia, i.e., ST depression at least 1 mm in 2 contiguous leads or T wave inversion > 3 mm or any dynamic ST shift or transient ST elevation.
- Written informed consent dated and signed

Exclusion Criteria:

- Age < 21 years.
- Any contraindication to UFH or fondaparinux
- Contraindication for angiography or PCI at baseline
- Subjects requiring urgent (<120 minutes) coronary angiography as characterized by those with:
- refractory or recurrent angina associated with dynamic ST-deviation

- heart failure
- life-threatening arrhythmias
- hemodynamic instability
- Subjects already receiving treatment with enoxaparin (or other LMWH), bivalirudin or UFH for treatment of the qualifying events unless the last administered (intravenous(i.v.) or s.c.) dose was:
- ≥ 8 hours for low molecular weight heparin (LMWH)
- ≥60 minutes for bivalirudin
- ≥90 minutes for unfractionated heparin (UFH)
- Hemorrhagic stroke within the last 12 months.
- Indication for anti-coagulation other than acute coronary syndrome (ACS) during the index hospitalization.
- Pregnancy or women of childbearing potential who are not using an effective method of contraception.
- Co-morbid condition with life expectancy less than 6 months.
- Currently receiving an experimental pharmacological agent.
- Revascularization procedure already performed for the qualifying event.
- Severe renal insufficiency (i.e., estimated creatinine clearance <20 ml/min)

Following angiography and confirmation that the subject is to undergo PCI, the subject must also meet all of the following additional criteria in order to be randomised:

- Subjects will have received at least 1 dose of open-label fondaparinux
- The most recent dose of open-label fondaparinux will not have been more than 24 hours before the start of the PCI procedure.

## Contacts and Locations

### Locations

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## Investigators

| | | |
|---|---|---|
| Study Director: | GSK Clinical Trials | GlaxoSmithKline |

## More Information

Results Publications:

The FUTURA/OASIS-8 Trial Group. Low-dose vs standard-dose unfractionated heparin for percutaneous coronary intervention in acute coronary syndromes treated with fondaparinux. The FUTURA/OASIS-8 randomized trial. JAMA. 2010; 304(12):1339-1349.

| | |
|---|---|
| Responsible Party: | GlaxoSmithKline |
| Study ID Numbers: | 108888 |
| Health Authority: | Japan: Ministry of Health, Labor and Welfare<br>United Kingdom: Medicines and Healthcare Products Regulatory Agency<br>Argentina: Ministry of Health - A.N.M.A.T<br>Brazil: ANVISA<br>Russia: Russian Ministry of Health<br>Canada: Health Canada<br>India: Drugs Controlle Gerneral of India<br>South Korea: Food and Drug Administration<br>United States: Food and Drug Administration<br>Europe: European Medicines Agency<br>Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) |

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# Study Results

## Participant Flow

### Pre-Assignment Details

All participants (par.) received open-label (OL) fondaparinux (fond.). Par. indicated for percutaneous coronary intervention (PCI) were randomized to low- or standard-dose unfractionated heparin during PCI. Post-PCI, par. could resume OL fond. Par. not indicated for PCI weren’t randomized and continued OL fond.

### Reporting Groups

| | Description |
|---|---|
| Open-label Fondaparinux 2.5 mg | Open-label (OL) fondaparinux syringes pre-filled with 2.5 milligrams (mg), administered subcutaneously (s.c.) once daily for up to 8 days or hospital discharge, whichever was earlier, for those participants not indicated for percutaneous coronary intervention (PCI) and not randomized |
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Overall Study

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Started | 1209 | 1024 | 1002 |
| Completed | 754 | 684 | 663 |
| Not Completed | 455 | 340 | 339 |
| Adverse Event | 9 | 7 | 6 |
| Physician Decision | 304 | 271 | 255 |
| Withdrawal by Subject | 1 | 7 | 5 |
| Bleeding Event | 11 | 16 | 21 |
| Required Protocol-prohibited Therapy | 17 | 5 | 7 |
| Qualifying Condition Not Present | 29 | 14 | 16 |
| Verbatim Reason on the Case Report Form | 74 | 20 | 29 |
| Did Not Receive Study Drug | 10 | 0 | 0 |

## Baseline Characteristics

### Reporting Groups

| | Description |
|---|---|
| Open-label Fondaparinux 2.5 | Open-label (OL) fondaparinux syringes pre-filled with 2.5 milligrams |

| | Description |
|---|---|
| mg | (mg), administered subcutaneously (s.c.) once daily for up to 8 days or hospital discharge, whichever was earlier, for those participants not indicated for percutaneous coronary intervention (PCI) and not randomized |
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Baseline Measures

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI | Total |
|---|---|---|---|---|
| Number of Participants | 1209 | 1024 | 1002 | 3235 |
| Age, Continuous<br>[units: Years]<br>Mean (Standard Deviation) | 65.8 (11.07) | 65.3 (11.25) | 65.5 (11.10) | 65.5 (11.14) |
| Gender, Male/Female<br>[units: Participants] | | | | |
| Female | 486 | 335 | 316 | 1137 |
| Male | 723 | 689 | 686 | 2098 |
| Race/Ethnicity, Customized [1]<br>[units: participants] | | | | |
| South Asian | 249 | 151 | 150 | 550 |
| Other Asian | 63 | 61 | 61 | 185 |
| Arab | 3 | 5 | 3 | 11 |
| Black African | 4 | 1 | 3 | 8 |
| European | 830 | 768 | 749 | 2347 |
| Native Latin | 57 | 37 | 33 | 127 |
| Other - verbatim reason collected on the CRF | 2 | 1 | 2 | 5 |
| Missing | 1 | 0 | 1 | 2 |

[1] CRF, case report form.

## Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Participants With Composite of Major Bleeding, Minor Bleeding, or Major Vascular Access Site Complications During the Peri-PCI Period |
| Measure Description | The peri-percutaneous coronary intervention (peri-PCI) period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Major and minor bleeding events were adjudicated by a blinded central independent adjudication committee (CIAC). Major vascular access site complications comprised large hematoma, pseudoaneurysm requiring treatment, aterio-venous fistula, or other vascular procedures related to the access site. |
| Time Frame | Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total) |
| Safety Issue? | Yes |

### Analysis Population Description

Intent-to-Treat (ITT) Population: all randomized participants

### Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially |

| | Description |
|---|---|
| | available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants With Composite of Major Bleeding, Minor Bleeding, or Major Vascular Access Site Complications During the Peri-PCI Period<br>[units: participants] | 48 | 58 |

Statistical Analysis 1 for Number of Participants With Composite of Major Bleeding, Minor Bleeding, or Major Vascular Access Site Complications During the Peri-PCI Period

| | |
|---|---|
| Groups | OL Fondaparinux Background + Low Dose UFH During PCI, OL Fondaparinux Background + Standard Dose UFH During PCI |
| Method | Regression, Logistic |
| P-Value | 0.267 |
| Odds Ratio (OR) | 0.80 |
| 95% Confidence Interval | 0.54 to 1.19 |

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

[Not specified.]

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Participants With Composite of Major Bleeding During the Peri-PCI Period, With Death, MI, or TVR at Day 30 |
| Measure Description | The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Assessment of death, myocardial infarction (MI) and target vessel revascularisation (TVR) was performed at Day 30. Major bleeding, MI and TVR were adjudicated by a blinded CIAC. |
| Time Frame | Peri-PCI period for major bleeding (during the time from randomization up to 48 hours after the end of PCI [typically 49 hours total] ) and from randomization up to Day 30 for death, MI, or TVR |

| | |
|---|---|
| Safety Issue? | Yes |

## Analysis Population Description

ITT Population

## Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants With Composite of Major Bleeding During the Peri-PCI Period, With Death, MI, or TVR at Day 30 [units: participants] | 59 | 39 |

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Participants With Major Bleeding During the Peri-PCI Period |
| Measure Description | The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Major bleeding, MI and TVR were adjudicated by a blinded CIAC. |
| Time Frame | Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total) |
| Safety Issue? | Yes |

Analysis Population Description

ITT Population

Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once |

| | Description |
|---|---|
| + Low Dose UFH During PCI | daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants With Major Bleeding During the Peri-PCI Period [units: participants] | 14 | 12 |

4. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Participants With Minor Bleeding During the Peri-PCI Period |
| Measure Description | The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Minor bleeding events were adjudicated by a blinded CIAC. |
| Time Frame | Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total) |
| Safety Issue? | Yes |

## Analysis Population Description

ITT Population

## Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive |

| | Description |
|---|---|
| | blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants With Minor Bleeding During the Peri-PCI Period [units: participants] | 7 | 17 |

5. Secondary Outcome Measure:

| Measure Title | Number of Participants With Major Vascular Access Site Complications During the Peri-PCI Period |
|---|---|
| Measure Description | The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Major vascular access site complications included: large hematoma, pseudoaneurysm requiring treatment, arterio-venous fistula, or other vascular procedures related to the access site. |

| | |
|---|---|
| Time Frame | Peri-PCI Period: occurred at randomization (from randomization to 48 hours after end of PCI procedure, typically 49 hours total) |
| Safety Issue? | Yes |

## Analysis Population Description

ITT Population

## Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants With Major Vascular Access Site Complications During the Peri-PCI Period<br>[units: participants] | 33 | 43 |

6. Secondary Outcome Measure:

| Measure Title | Number of Participants With Major PCI-related Procedural Complications |
|---|---|
| Measure Description | Major PCI-related procedural complications included: abrupt vessel closure, a new angiographic filling defect representing either angiographic thrombus or major dissection with reduced flow, no-reflow phenomenon, or catheter-related thrombus. Investigator reports of catheter-related thrombus were defined as suspected catheter-related thrombus events, and were adjudicated by a blinded CIAC. |
| Time Frame | During PCI procedure: immediately after randomization (approximately 10-75 minutes) |
| Safety Issue? | Yes |

Analysis Population Description

ITT Population

Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants With Major PCI-related Procedural Complications | | |

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| [units: participants] | | |
| Abrupt Vessel Closure | 10 | 17 |
| New Angiographic Thrombus | 11 | 8 |
| Suspected Catheter-related Thrombus | 4 | 3 |
| Catheter-related Thrombus-Adjudicated | 4 | 1 |
| No-reflow Phenomenon | 20 | 22 |
| New Major Dissection with Reduced Flow | 10 | 10 |

7. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Participants With Composite of Death, MI or TVR During the Peri-PCI Period and at Day 30 |
| Measure Description | The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Assessment of composite of death, MI, or TVR was performed both during the peri-PCI period and at Day 30. MI and TVR events were adjudicated by a blinded CIAC. |
| Time Frame | Peri-PCI (during the time from randomization up to 48 hours after the end of PCI, typically 49 hours total) and from randomization up to Day 30 |
| Safety Issue? | Yes |

## Analysis Population Description

ITT Population

## Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants With Composite of Death, MI or TVR During the Peri-PCI Period and at Day 30<br>[units: participants] | | |
| Composite of death, MI, and TVR Peri-PCI | 23 | 19 |
| Composite of death, MI, and TVR at Day 30 | 46 | 29 |

8. Secondary Outcome Measure:

| Measure Title | Number of Participants Experiencing Death, MI, TVR, Definite/Probable Stent Thrombosis, or Stroke, Assessed Separately During the Peri-PCI Period and at Day 30 |
|---|---|
| Measure Description | The peri-PCI period was defined as the period during the time from randomization up to 48 hours after the end of the PCI procedure, typically 49 hours total. Assessment of death, MI, TVR, definite/probable stent thrombosis, or stroke was performed during the peri-PCI period and at Day 30. MI, TVR, definite/probable stent thrombosis, and stroke events were adjudicated by a blinded CIAC. |
| Time Frame | Peri-PCI (during the time from randomization up to 48 hours after the end of PCI, typically 49 hours total) and from randomization up to Day 30 |

| | |
|---|---|
| Safety Issue? | Yes |

## Analysis Population Description

ITT Population

## Reporting Groups

| | Description |
|---|---|
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

## Measured Values

| | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|
| Number of Participants Analyzed | 1024 | 1002 |
| Number of Participants Experiencing Death, MI, TVR, Definite/Probable Stent Thrombosis, or Stroke, Assessed Separately During the Peri-PCI Period and at Day 30<br>[units: participants] | | |
| Death during peri-PCI period | 1 | 2 |
| MI during peri-PCI period | 20 | 16 |
| TVR during peri-PCI period | 3 | 2 |
| Definite/Probable Stent Thrombosis during peri-PCI | 1 | 2 |
| Stroke during peri-PCI | 3 | 5 |
| Death at Day 30 | 8 | 6 |
| MI at Day 30 | 31 | 25 |
| TVR at Day 30 | 9 | 3 |
| Definite/Probable Stent Thrombosis at Day 30 | 12 | 5 |
| Stroke at Day 30 | 5 | 5 |

## Reported Adverse Events

### Reporting Groups

| | Description |
|---|---|
| Open-label Fondaparinux 2.5 mg | Open-label (OL) fondaparinux syringes pre-filled with 2.5 milligrams (mg), administered subcutaneously (s.c.) once daily for up to 8 days or hospital discharge, whichever was earlier, for those participants not indicated for percutaneous coronary intervention (PCI) and not randomized |
| OL Fondaparinux Background + Low Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded low-dose unfractionated heparin (UFH) (50 units/kilogram [U/kg], which was not adjusted for planned glycoprotein [GP] IIb/IIIa use or activated clotting time [ACT]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) may have been considered for randomization. |
| OL Fondaparinux Background + Standard Dose UFH During PCI | OL fondaparinux syringes pre-filled with 2.5 mg, administered s.c. once daily for up to 8 days or hospital discharge, whichever was earlier. Participants indicated for PCI were randomized to receive adjunctive blinded standard dose UFH (based on planned GPIIb/IIIa inhibitor use: 60 U/kg; no planned use: 85 U/kg and adjusted based on ACT [maximum two additional bolus doses]). Participants who presented in the catheterization laboratory and who were receiving commercially available fondaparinux prescribed for the initial treatment of UA/NSTEMI may have been considered for randomization. |

### Time Frame

Adverse events (AEs) and serious adverse events (SAEs) were collected from the start of fondaparinux until the follow-up at 30 days after randomization or angiography.

Additional Description

Per the protocol, study outcome events (including bleeding, death, myocardial infarction [MI] and stroke, and other disease-related events) were not to be reported as AEs/SAEs.

Serious Adverse Events

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Total # participants affected/at risk | 48/1209 (3.97%) | 28/1024 (2.73%) | 20/1002 (2%) |
| Blood and lymphatic system disorders | | | |
| Anemia of chronic disease †[A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Hemolytic anemia †[A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Cardiac disorders | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Atrial thrombosis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Cardiac tamponade † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Pericardial effusion † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Gastrointestinal disorders | | | |
| Abdominal pain † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Colitis ischaemic † [A] | | | |
| # participants affected/at | 1/1209 | 0/1024 (0%) | 0/1002 (0%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| risk | (0.08%) | | |
| # events | | | |
| Enterocolitis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Esophageal spasm † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Esophagitis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Fecaloma † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Intestinal ischemia † [A] | | | |
| # participants affected/at | 1/1209 | 0/1024 (0%) | 0/1002 (0%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| risk | (0.08%) | | |
| # events | | | |
| General disorders | | | |
| Impaired healing † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Non-cardiac chest pain † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 1/1024 (0.1%) | 2/1002 (0.2%) |
| # events | | | |
| Hepatobiliary disorders | | | |
| Cholangitis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Cholecystitis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| # events | | | |
| Infections and infestations | | | |
| Anal abscess † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Arthritis bacterial † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Bronchopneumonia † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Cellulitis † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Cholecystitis infective † [A] | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Gastroenteritis viral † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Lower respiratory tract infection † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Pneumonia † [A] | | | |
| # participants affected/at risk | 4/1209 (0.33%) | 2/1024 (0.2%) | 2/1002 (0.2%) |
| # events | | | |
| Post procedural infection † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Pyelonephritis acute † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Sepsis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Septic shock † [A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Urosepsis † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Injury, poisoning and procedural complications | | | |
| Contrast media reaction † [A] | | | |
| # participants affected/at | 1/1209 | 0/1024 (0%) | 1/1002 (0.1%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| risk | (0.08%) | | |
| # events | | | |
| Postoperative wound complication † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Postoperative wound infection † [A] | | | |
| # participants affected/at risk | 3/1209 (0.25%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Vascular access complication † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Vascular pseudoaneurysm † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| # events | | | |
| Investigations | | | |
| Hepatic enzyme increased † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Platelet count decreased † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Metabolism and nutrition disorders | | | |
| Acidosis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| and polyps) | | | |
| Brain neoplasm † [A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Colon cancer † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Esophageal adenocarcinoma † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Gastric cancer † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Hepatic neoplasm † [A] | | | |
| # participants affected/at | 1/1209 | 0/1024 (0%) | 0/1002 (0%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| risk | (0.08%) | | |
| # events | | | |
| Lung adenocarcinoma † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Multiple myeloma † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Neoplasm prostate † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Pancreatic carcinoma metastatic † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Nervous system | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| disorders | | | |
| Hepatic encephalophathy † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Transient ischemic attack † [A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Vascular encephalopathy † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Renal and urinary disorders | | | |
| Nephropathy toxic † [A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 6/1024 (0.59%) | 2/1002 (0.2%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| # events | | | |
| Renal artery stenosis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Renal failure † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 3/1002 (0.3%) |
| # events | | | |
| Renal failure acute † [A] | | | |
| # participants affected/at risk | 3/1209 (0.25%) | 3/1024 (0.29%) | 0/1002 (0%) |
| # events | | | |
| Urethral stenosis † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| disease † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Pleural hemorrhage † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 0/1024 (0%) | 1/1002 (0.1%) |
| # events | | | |
| Pneumothorax † [A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Pulmonary edema † [A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Pulmonary embolism † [A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 1/1024 (0.1%) | 1/1002 (0.1%) |
| # events | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Respiratory depression † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Respiratory failure † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |
| Vascular disorders | | | |
| Aortic dissection † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 1/1024 (0.1%) | 1/1002 (0.1%) |
| # events | | | |
| Deep vein thrombosis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Extremity necrosis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| # events | | | |
| Hypertension † [A] | | | |
| # participants affected/at risk | 0/1209 (0%) | 1/1024 (0.1%) | 0/1002 (0%) |
| # events | | | |
| Thrombophlebitis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 0/1024 (0%) | 0/1002 (0%) |
| # events | | | |

† Indicates events were collected by systematic assessment.

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## Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0.5%

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Total # participants affected/at risk | 117/1209 (9.68%) | 100/1024 (9.77%) | 113/1002 (11.28%) |
| Gastrointestinal | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| disorders | | | |
| Constipation † [A] | | | |
| # participants affected/at risk | 10/1209 (0.83%) | 5/1024 (0.49%) | 8/1002 (0.8%) |
| # events | | | |
| Diarrhea † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 9/1024 (0.88%) | 7/1002 (0.7%) |
| # events | | | |
| Gastritis † [A] | | | |
| # participants affected/at risk | 15/1209 (1.24%) | 0/1024 (0%) | 2/1002 (0.2%) |
| # events | | | |
| Nausea † [A] | | | |
| # participants affected/at risk | 7/1209 (0.58%) | 4/1024 (0.39%) | 5/1002 (0.5%) |
| # events | | | |
| Vomiting † [A] | | | |
| # participants affected/at risk | 6/1209 (0.5%) | 9/1024 (0.88%) | 5/1002 (0.5%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| # events | | | |
| General disorders | | | |
| Asthenia † [A] | | | |
| # participants affected/at risk | 13/1209 (1.08%) | 7/1024 (0.68%) | 3/1002 (0.3%) |
| # events | | | |
| Non-cardiac chest pain † [A] | | | |
| # participants affected/at risk | 4/1209 (0.33%) | 1/1024 (0.1%) | 6/1002 (0.6%) |
| # events | | | |
| Pyrexia † [A] | | | |
| # participants affected/at risk | 13/1209 (1.08%) | 11/1024 (1.07%) | 16/1002 (1.6%) |
| # events | | | |
| Infections and infestations | | | |
| Nasopharyngitis † [A] | | | |
| # participants affected/at risk | 1/1209 (0.08%) | 2/1024 (0.2%) | 7/1002 (0.7%) |
| # events | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Urinary tract infection † [A] | | | |
| # participants affected/at risk | 15/1209 (1.24%) | 5/1024 (0.49%) | 5/1002 (0.5%) |
| # events | | | |
| Injury, poisoning and procedural complications | | | |
| Post procedural discharge † [A] | | | |
| # participants affected/at risk | 11/1209 (0.91%) | 9/1024 (0.88%) | 15/1002 (1.5%) |
| # events | | | |
| Metabolism and nutrition disorders | | | |
| Hypercholesterolemia † [A] | | | |
| # participants affected/at risk | 7/1209 (0.58%) | 3/1024 (0.29%) | 5/1002 (0.5%) |
| # events | | | |
| Musculoskeletal and connective tissue disorders | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| Back pain † [A] | | | |
| # participants affected/at risk | 8/1209 (0.66%) | 7/1024 (0.68%) | 1/1002 (0.1%) |
| # events | | | |
| Nervous system disorders | | | |
| Carotid artery stenosis † [A] | | | |
| # participants affected/at risk | 7/1209 (0.58%) | 7/1024 (0.68%) | 4/1002 (0.4%) |
| # events | | | |
| Dizziness † [A] | | | |
| # participants affected/at risk | 5/1209 (0.41%) | 11/1024 (1.07%) | 2/1002 (0.2%) |
| # events | | | |
| Headache † [A] | | | |
| # participants affected/at risk | 18/1209 (1.49%) | 24/1024 (2.34%) | 28/1002 (2.79%) |
| # events | | | |
| Psychiatric disorders | | | |
| Insomnia † [A] | | | |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| # participants affected/at risk | 2/1209 (0.17%) | 6/1024 (0.59%) | 2/1002 (0.2%) |
| # events | | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough †[A] | | | |
| # participants affected/at risk | 3/1209 (0.25%) | 4/1024 (0.39%) | 10/1002 (1%) |
| # events | | | |
| Dyspnea †[A] | | | |
| # participants affected/at risk | 8/1209 (0.66%) | 6/1024 (0.59%) | 3/1002 (0.3%) |
| # events | | | |
| Vascular disorders | | | |
| Hematoma †[A] | | | |
| # participants affected/at risk | 2/1209 (0.17%) | 6/1024 (0.59%) | 3/1002 (0.3%) |
| # events | | | |
| Hypertension †[A] | | | |
| # participants affected/at | 2/1209 | 0/1024 (0%) | 7/1002 (0.7%) |

| | Open-label Fondaparinux 2.5 mg | OL Fondaparinux Background + Low Dose UFH During PCI | OL Fondaparinux Background + Standard Dose UFH During PCI |
|---|---|---|---|
| risk | (0.17%) | | |
| # events | | | |
| Hypotension † [A] | | | |
| # participants affected/at risk | 7/1209 (0.58%) | 6/1024 (0.59%) | 10/1002 (1%) |
| # events | | | |

† Indicates events were collected by systematic assessment.

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## More Information

Certain Agreements:

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

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

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Limitations and Caveats:

Results Point of Contact:

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