# Phase II Study to Compare MDCO-2010 vs Placebo and Tranexamic Acid in Patients Undergoing Cardiac Surgery



ClinicalTrials.gov Identifier: NCT01530399

Recruitment Status : Terminated (Safety)
First Posted : February 9, 2012
Results First Posted : December 10, 2015
Last Update Posted : December 10, 2015

**Sponsor:**

The Medicines Company

**Information provided by (Responsible Party):**

The Medicines Company



| | |
|---|---|
| **Study Type** | Interventional |
| **Study Design** | Allocation: Randomized; Intervention Model: Parallel Assignment;<br>Masking: Triple (Participant, Investigator, Outcomes Assessor); Primary Purpose: Treatment |
| **Condition** | Bleeding |
| **Interventions** | Drug: MDCO 1<br>Drug: MDCO 2<br>Drug: MDCO 3<br>Drug: MDCO 4<br>Drug: Tranexamic Acid<br>Drug: Saline |
| **Enrollment** | 44 |

## Participant Flow

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| | |
|---|---|
| Recruitment Details | |
| Pre-assignment Details | |

| Arm/Group Title | MDCO 1 | MDCO 2 | MDCO 3 | MDCO 4 | Saline | Tranexamic Acid |
|---|---|---|---|---|---|---|

| ▼ Arm/Group Description | MDCO-2010 Dose 1: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 1: load 15 µg/kg; infusion 30 µg/kg/h; CPB prime 0.11 µg/mL priming volume | MDCO-2010 Dose 2: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 2: load 30 µg/kg; infusion 60 µg/kg/h; CPB prime 0.22 µg/mL priming volume | MDCO-2010 Dose 3: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 3: load 60 µg/kg ; infusion 120 µg/kg/h; CPB prime 0.44 µg/mL priming volume | MDCO-2010 Dose 4: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 4: load 90 µg/kg; infusion 180 µg/kg/h; CPB prime 0.65 µg/mL priming volume | Tranexamic Acid: Tranexamic acid will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with tranexamic acid. The flow rates will be the same as for MDCO-2010. | saline: A loading dose of saline will be followed by a continuous infusion of saline until sternal closure. In addition, the CPB reservoir will be primed with saline. The flow rates will be the same as for MDCO-2010. |
|---|---|---|---|---|---|---|
| Period Title: **Overall Study** | | | | | | |
| Started | 8 | 10 | 8 | 10 | 6 | 7 |
| Completed | 7 | 8 | 7 | 10 | 6 | 6 |
| Not Completed | 1 | 2 | 1 | 0 | 0 | 1 |

## Baseline Characteristics

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| Arm/Group Title | MDCO 1 | MDCO 2 | MDCO 3 | MDCO 4 | Saline | Tranexamic Acid | Total |
|---|---|---|---|---|---|---|---|
| Arm/Group Description | MDCO-2010 Dose 1: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 1: load 15 µg/kg; infusion 30 µg/kg/h; CPB prime 0.11 µg/mL priming volume | MDCO-2010 Dose 2: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 2: load 30 µg/kg; infusion 60 µg/kg/h; CPB prime 0.22 µg/mL priming volume | MDCO-2010 Dose 3: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 3: load 60 µg/kg ; infusion 120 µg/kg/h; CPB prime 0.44 µg/mL priming volume | MDCO-2010 Dose 4: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 4: load 90 µg/kg; infusion 180 µg/kg/h; CPB prime 0.65 µg/mL priming volume | Tranexamic Acid: Tranexamic acid will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with tranexamic acid. The flow rates will be the same as for MDCO-2010. | saline: A loading dose of saline will be followed by a continuous infusion of saline until sternal closure. In addition, the CPB reservoir will be primed with saline. The flow rates will be the same as for MDCO-2010. | Total of all reporting groups |
| Overall Number of Baseline Participants | 8 | 10 | 8 | 10 | 6 | 7 | 49 |

Baseline Participants

| ▼ Baseline Analysis Population Description | [Not Specified] | | | | | | |
|---|---|---|---|---|---|---|---|
| Age, Continuous<br><br>Median (Inter-Quartile Range)<br>Unit of measure: Years | | | | | | | |
| | Number Analyzed | 8 participants | 10 participants | 8 participants | 10 participants | 6 participants | 7 participants | 49 participants |
| | | 71 (64 to 75) | 70 (57 to 73) | 66 (60 to 79) | 73 (68 to 73) | 66 (60 to 71) | 58 (52 to 62) | 69 (61 to 73) |
| Sex: Female, Male<br>Measure Type: Count of Participants<br>Unit of measure: Participants | | | | | | | |
| | Number Analyzed | 8 participants | 10 participants | 8 participants | 10 participants | 6 participants | 7 participants | 49 participants |
| | Female | 1 12.5% | 2 20.0% | 1 12.5% | 2 20.0% | 2 33.3% | 0 0.0% | 8 16.3% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Male | 7 87.5% | 8 80.0% | 7 87.5% | 8 80.0% | 4 66.7% | 7 100.0% | 41 83.7% |
| Region of Enrollment<br><br>Measure Type: Number<br>Unit of measure: Participants | Number Analyzed | 8 participants | 10 participants | 8 participants | 10 participants | 6 participants | 7 participants | 49 participants |
| Germany | | 6 | 7 | 5 | 7 | 4 | 4 | 33 |
| Switzerland | | 2 | 3 | 3 | 3 | 2 | 3 | 16 |

## Outcome Measures

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1. Primary Outcome

| | |
|---|---|
| Title | Chest Tube Drainage at 12 Hours After Surgery |
| Description | [Not Specified] |
| Time Frame | 12 hours post CABG |

Outcome Measure Data

Analysis Population Description

[Not Specified]

| Arm/Group Title | MDCO 1 | MDCO 2 | MDCO 3 | MDCO 4 | Saline | Tr |
|---|---|---|---|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| ▼ Arm/Group Description: | MDCO-2010 Dose 1: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 1: load 15 µg/kg; infusion 30 µg/kg/h; CPB prime 0.11 µg/mL priming volume | MDCO-2010 Dose 2: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 2: load 30 µg/kg; infusion 60 µg/kg/h; CPB prime 0.22 µg/mL priming volume | MDCO-2010 Dose 3: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 3: load 60 µg/kg ; infusion 120 µg/kg/h; CPB prime 0.44 µg/mL priming volume | MDCO-2010 Dose 4: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 4: load 90 µg/kg; infusion 180 µg/kg/h; CPB prime 0.65 µg/mL priming volume | Tranexamic Acid: Tranexamic acid will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with tranexamic acid. The flow rates will be the same as for MDCO-2010. | sali dos be f con of s clos the will sali rate sam 201 |
| Overall Number of Participants Analyzed | 7 | 7 | 6 | 10 | 6 | |
| Median (Inter-Quartile Range) Unit of Measure: mL | | | | | | |
| | 600 (300 to 970) | 580 (420 to 880) | 480 (350 to 700) | 453 (415 to 645) | 645 (400 to 1040) | |

## Adverse Events

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| | |
|---|---|
| Time Frame | 30 (+5) days post treatment |
| Adverse Event Reporting Description | [Not Specified] |

| Arm/Group Title | MDCO 1 | MDCO 2 | MDCO 3 | MDCO 4 | Saline | Tranexamic Acid |
|---|---|---|---|---|---|---|
| Arm/Group Description | MDCO-2010 Dose 1: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 1: load 15 µg/kg; infusion 30 µg/kg/h; CPB prime 0.11 µg/mL priming volume | MDCO-2010 Dose 2: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 2: load 30 µg/kg; infusion 60 µg/kg/h; CPB prime 0.22 µg/mL priming volume | MDCO-2010 Dose 3: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 3: load 60 µg/kg ; infusion 120 µg/kg/h; CPB prime 0.44 µg/mL priming volume | MDCO-2010 Dose 4: MDCO-2010 will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with MDCO-2010. MDCO 4: load 90 µg/kg; infusion 180 µg/kg/h; CPB prime 0.65 µg/mL priming volume | Tranexamic Acid: Tranexamic acid will be administered as a loading dose followed by a continuous infusion until sternal closure. In addition, the CPB reservoir will be primed with tranexamic acid. The flow rates will be the same as for MDCO-2010. | saline: A loading dose of saline will be followed by a continuous infusion of saline until sternal closure. In addition, the CPB reservoir will be primed with saline. The flow rates will be the same as for MDCO-2010. |

### All-Cause Mortality

| | MDCO 1 | MDCO 2 | MDCO 3 | MDCO 4 | Saline | Tranexamic Acid |
|---|---|---|---|---|---|---|
| | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) |
| Total | --/-- | --/-- | --/-- | --/-- | --/-- | --/-- |

### Serious Adverse Events

| | MDCO 1 | MDCO 2 | MDCO 3 | MDCO 4 | Saline | Tranexamic Acid |
|---|---|---|---|---|---|---|
| | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) |
| Total | 2/7 (28.57%) | 2/8 (25.00%) | 1/7 (14.29%) | 2/10 (20.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Blood and lymphatic system disorders | | | | | | |
| Haemorrhagic anaemia † 1 | 1/7 (14.29%) | 0/8 (0.00%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Cardiac disorders | | | | | | |
| Cardiac tamponade † 1 | 0/7 (0.00%) | 1/8 (12.50%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Coronary artery occlusion † 1 | 0/7 (0.00%) | 1/8 (12.50%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Low cardiac output syndrome † 1 | 0/7 (0.00%) | 1/8 (12.50%) | 1/7 (14.29%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Injury, poisoning and procedural | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| and procedural complications | | | | | | |
| Vascular graft thrombosis † 1 | 0/7 (0.00%) | 0/8 (0.00%) | 0/7 (0.00%) | 1/10 (10.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Nervous system disorders | | | | | | |
| Ischaemic stroke † 1 | 1/7 (14.29%) | 0/8 (0.00%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Renal and urinary disorders | | | | | | |
| Renal failure † 1 | 1/7 (14.29%) | 0/8 (0.00%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Respiratory, thoracic and mediastinal disorders | | | | | | |
| Respiratory failure † 1 | 1/7 (14.29%) | 0/8 (0.00%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Vascular disorders | | | | | | |
| Arterial thrombosis limb † 1 | 0/7 (0.00%) | 0/8 (0.00%) | 0/7 (0.00%) | 1/10 (10.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Extremity necrosis † 1 | 1/7 (14.29%) | 0/8 (0.00%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Jugular vein thrombosis † 1 | 0/7 (0.00%) | 0/8 (0.00%) | 0/7 (0.00%) | 1/10 (10.00%) | 0/6 (0.00%) | 0/6 (0.00%) |

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA (Unspecified)

## Other (Not Including Serious) Adverse Events

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|---|---|
| Frequency Threshold for Reporting Other Adverse Events | 5% |

| | MDCO 1 | MDCO 2 | MDCO 3 | MDCO 4 | Saline | Tranexamic Acid |
|---|---|---|---|---|---|---|
| | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) | Affected / at Risk (%) |
| Total | 5/7 (71.43%) | 7/8 (87.50%) | 4/7 (57.14%) | 7/10 (70.00%) | 5/6 (83.33%) | 4/6 (66.67%) |
| Blood and lymphatic system disorders | | | | | | |
| Troponin T increased † 1 | 1/7 (14.29%) | 2/8 (25.00%) | 1/7 (14.29%) | 1/10 (10.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Cardiac disorders | | | | | | |
| Atrial fibrillation † 1 | 1/7 (14.29%) | 2/8 (25.00%) | 1/7 (14.29%) | 2/10 (20.00%) | 1/6 (16.67%) | 2/6 (33.33%) |
| Gastrointestinal disorders | | | | | | |
| Nausea † 1 | 2/7 (28.57%) | 1/8 (12.50%) | 0/7 (0.00%) | 1/10 (10.00%) | 2/6 (33.33%) | 0/6 (0.00%) |
| AST increased † 1 | 0/7 (0.00%) | 0/8 (0.00%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 2/6 (33.33%) |
| Hepatobiliary disorders | | | | | | |
| AST increased † 1 | 0/7 (0.00%) | 2/8 (25.00%) | 0/7 (0.00%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |
| Renal and urinary disorders | | | | | | |
| Urinary tract infection † 1 | 0/7 (0.00%) | 0/8 (0.00%) | 1/7 (14.29%) | 2/10 (20.00%) | 2/6 (33.33%) | 0/6 (0.00%) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Infection †1 | | | | | | |
| Respiratory, thoracic and mediastinal disorders | | | | | | |
| Pleural effusion †1 | 3/7 (42.86%) | 2/8 (25.00%) | 1/7 (14.29%) | 1/10 (10.00%) | 1/6 (16.67%) | 0/6 (0.00%) |
| Pneumothorax †1 | 0/7 (0.00%) | 2/8 (25.00%) | 1/7 (14.29%) | 0/10 (0.00%) | 0/6 (0.00%) | 0/6 (0.00%) |

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA (Unspecified)

## Limitations and Caveats

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[Not Specified]

## More Information

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### 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.

After initial multicenter results communications are published, or after 12 months from study closure (whichever occurs first), sponsor can review results communications prior to submission and can embargo submissions for a period of 45 days from the time submitted to the sponsor for review, agreeing to resolve differences of opinion or interpretation through scientific debate. Sponsor can request further delay for an additional 90 days to file any patent applications if deemed necessary

### Results Point of Contact

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|---|---|
| Responsible Party: | The Medicines Company |
| ClinicalTrials.gov Identifier: | NCT01530399 History of Changes |
| Other Study ID Numbers: | **TMC-MDC-11-01** |
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| First Posted: | February 9, 2012 |
| Results First Submitted: | November 4, 2015 |
| Results First Posted: | December 10, 2015 |
| Last Update Posted: | December 10, 2015 |