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Trial record **1 of 1** for: NCT00508924
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Study on Safety and Effectiveness of Three Doses of Argatroban as Anticoagulant in Percutaneous Coronary Intervention (PCI)

This study has been completed.

Sponsor:
Mitsubishi Tanabe Pharma Corporation

Information provided by:
Mitsubishi Tanabe Pharma Corporation

ClinicalTrials.gov Identifier:
NCT00508924

First received: July 26, 2007
Last updated: November 6, 2012
Last verified: November 2012
History of Changes

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

Results First Received: November 6, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Pharmacokinetics/Dynamics Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Coronary Artery Disease Angina, Unstable
Interventions:	Drug: Argatroban Drug: Heparin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

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

Reporting Groups

	Description
ARG250	250μg/kg i.v. bolus of argatroban followed by infusion of 15μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG300	300μg/kg i.v. bolus followed by infusion of 20μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG350	350μg/kg i.v. bolus followed by infusion of 25μg/kg/min

	additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
Heparin	70-100 IU/kg i.v. bolus additional 2,000-5,000 IU boluses could be given in order to reach the target ACT level of 250 sec

Participant Flow: Overall Study

	ARG250	ARG300	ARG350	Heparin
STARTED	36	38	32	34
COMPLETED	36	38	31	33
NOT COMPLETED	0	0	1	1
Protocol Violation	0	0	1	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
ARG250	250μg/kg i.v. bolus of argatroban followed by infusion of 15μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG300	300μg/kg i.v. bolus followed by infusion of 20μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG350	350μg/kg i.v. bolus followed by infusion of 25μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
Heparin	70-100 IU/kg i.v. bolus additional 2,000-5,000 IU boluses could be given in order to reach the target ACT level of 250 sec
Total	Total of all reporting groups

Baseline Measures

	ARG250	ARG300	ARG350	Heparin	Total
Number of Participants [units: participants]	**36**	**38**	**32**	**34**	**140**
Age [units: years] Mean (Standard Deviation)	**63.4 (8.9)**	**65.5 (9.5)**	**68.3 (7.9)**	**65.9 (9.8)**	**65.7 (9.2)**
Gender [units: participants]					
Female	**11**	**8**	**9**	**5**	**33**
Male	**25**	**30**	**23**	**29**	**107**

Outcome Measures

Hide All Outcome Measures

1. Primary: Activated Clotting Time (ACT) Value After the First Dosing of Study Treatment. [Time Frame: 5 - 10 min after initial bolus]

Measure Type	Primary
Measure Title	Activated Clotting Time (ACT) Value After the First Dosing of Study Treatment.
Measure Description	No text entered.
Time Frame	5 - 10 min after initial bolus
Safety Issue	No

Population Description

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

Reporting Groups

	Description
ARG250	250μg/kg i.v. bolus of argatroban followed by infusion of 15μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG300	300μg/kg i.v. bolus followed by infusion of 20μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG350	350μg/kg i.v. bolus followed by infusion of 25μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
Heparin	70-100 IU/kg i.v. bolus additional 2,000-5,000 IU boluses could be given in order to reach the target ACT level of 250 sec

Measured Values

	ARG250	**ARG300**	**ARG350**	**Heparin**
Number of Participants Analyzed [units: participants]	**36**	**38**	**31**	**33**
Activated Clotting Time (ACT) Value After the First Dosing of Study Treatment. [units: second] Median (Inter-Quartile Range)	**301.0 (262.8 to 330.0)**	**330.0 (270.0 to 365.0)**	**354.0 (307.0 to 391.0)**	**237.5 (198.0 to 284.0)**

No statistical analysis provided for Activated Clotting Time (ACT) Value After the First Dosing of Study Treatment.

2. Primary: Composite and Each of Death, Myocardial Infarction, and Urgent Revascularisation at Day 30, and Major Bleeding Events During Hospital Stay. [Time Frame: 30 Days]

Measure Type	Primary
Measure Title	Composite and Each of Death, Myocardial Infarction, and Urgent Revascularisation at Day 30, and Major Bleeding Events During Hospital Stay.
Measure Description	Composite end point (a): all cause death, myocardial infarction and urgent revascularization at Day30

	Composite end point (b): all cause death, myocardial infarction and urgent revascularization at Day30 as well as major bleeding events during hospital stay
Time Frame	30 Days
Safety Issue	No

Population Description

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

Reporting Groups

	Description
ARG250	250μg/kg i.v. bolus of argatroban followed by infusion of 15μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG300	300μg/kg i.v. bolus followed by infusion of 20μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG350	350μg/kg i.v. bolus followed by infusion of 25μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
Heparin	70-100 IU/kg i.v. bolus additional 2,000-5,000 IU boluses could be given in order to reach the target ACT level of 250 sec

Measured Values

	ARG250	ARG300	ARG350	Heparin
Number of Participants Analyzed [units: participants]	**36**	**38**	**31**	**33**
Composite and Each of Death, Myocardial Infarction, and Urgent Revascularisation at Day 30, and Major Bleeding Events During Hospital Stay. [units: participants]				
Composite end point (a)	**1**	**0**	**1**	**1**
Composite end point (b)	**1**	**0**	**1**	**2**
All cause death	**0**	**0**	**0**	**0**
Myocardial infarction	**0**	**0**	**1**	**1**
Urgent revascularization	**1**	**0**	**1**	**0**
Major bleeding	**0**	**0**	**0**	**1**

No statistical analysis provided for Composite and Each of Death, Myocardial Infarction, and Urgent Revascularisation at Day 30, and Major Bleeding Events During Hospital Stay.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
ARG250	250µg/kg i.v. bolus of argatroban followed by infusion of 15µg/kg/min additional 150µg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG300	300µg/kg i.v. bolus followed by infusion of 20µg/kg/min additional 150µg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG350	350µg/kg i.v. bolus followed by infusion of 25µg/kg/min additional 150µg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
Heparin	70-100 IU/kg i.v. bolus additional 2,000-5,000 IU boluses could be given in order to reach the target ACT level of 250 sec

Serious Adverse Events

	ARG250	ARG300	ARG350	Heparin
Total, serious adverse events				
# participants affected / at risk	**4/36 (11.11%)**	**5/38 (13.16%)**	**7/32 (21.88%)**	**4/34 (11.76%)**
Blood and lymphatic system disorders				
Anaemia [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**1/34 (2.94%)**
Cardiac disorders				
Acute myocardial infarction [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**1/34 (2.94%)**
Angina pectoris [1]				
# participants affected / at risk	**0/36 (0.00%)**	**1/38 (2.63%)**	**0/32 (0.00%)**	**0/34 (0.00%)**
Angina unstable [1]				
# participants affected / at risk	**1/36 (2.78%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**0/34 (0.00%)**
Artrial fibrillation [1]				
# participants affected / at risk	**1/36 (2.78%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**0/34 (0.00%)**
Coronary artery dissection [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**1/32 (3.13%)**	**0/34 (0.00%)**
Coronary artery occlusion [1]				
# participants affected / at risk	**1/36 (2.78%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**0/34 (0.00%)**
Myocardial infarction [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**1/32 (3.13%)**	**0/34 (0.00%)**
Gastrointestinal disorders				
Abdominal pain upper [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**1/32 (3.13%)**	**0/34 (0.00%)**
Retroperitoneal haematoma [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**1/34 (2.94%)**
General disorders				
Catheter site haemorrhage [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**1/32 (3.13%)**	**0/34 (0.00%)**

Chest pain [1]				
# participants affected / at risk	0/36 (0.00%)	1/38 (2.63%)	1/32 (3.13%)	0/34 (0.00%)
Immune system disorders				
Hypersensitivity [1]				
# participants affected / at risk	0/36 (0.00%)	1/38 (2.63%)	0/32 (0.00%)	0/34 (0.00%)
Infections and infestations				
Groin infection [1]				
# participants affected / at risk	0/36 (0.00%)	0/38 (0.00%)	0/32 (0.00%)	1/34 (2.94%)
Pneumonia [1]				
# participants affected / at risk	0/36 (0.00%)	0/38 (0.00%)	0/32 (0.00%)	1/34 (2.94%)
Injury, poisoning and procedural complications				
Lower limb fracture [1]				
# participants affected / at risk	1/36 (2.78%)	0/38 (0.00%)	0/32 (0.00%)	0/34 (0.00%)
Musculoskeletal and connective tissue disorders				
Rhabdomyolysis [1]				
# participants affected / at risk	0/36 (0.00%)	1/38 (2.63%)	0/32 (0.00%)	0/34 (0.00%)
Nervous system disorders				
Basilar migraine [1]				
# participants affected / at risk	0/36 (0.00%)	0/38 (0.00%)	1/32 (3.13%)	0/34 (0.00%)
Cerebrovascular accident [1]				
# participants affected / at risk	0/36 (0.00%)	1/38 (2.63%)	0/32 (0.00%)	0/34 (0.00%)
Syncope [1]				
# participants affected / at risk	0/36 (0.00%)	0/38 (0.00%)	1/32 (3.13%)	0/34 (0.00%)
Psychiatric disorders				
Panic attack [1]				
# participants affected / at risk	0/36 (0.00%)	1/38 (2.63%)	0/32 (0.00%)	0/34 (0.00%)
Vascular disorders				
Peripheral ischaemia [1]				
# participants affected / at risk	1/36 (2.78%)	0/38 (0.00%)	0/32 (0.00%)	0/34 (0.00%)

1 Term from vocabulary, MedDRA 9.0

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

ARG250	250μg/kg i.v. bolus of argatroban followed by infusion of 15μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG300	300μg/kg i.v. bolus followed by infusion of 20μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
ARG350	350μg/kg i.v. bolus followed by infusion of 25μg/kg/min additional 150μg/kg i.v. boluses (maximum 2 additional) could be given in order to reach the target ACT level of 250 sec
Heparin	70-100 IU/kg i.v. bolus additional 2,000-5,000 IU boluses could be given in order to reach the target ACT level of 250 sec

Other Adverse Events

	ARG250	ARG300	ARG350	Heparin
Total, other (not including serious) adverse events				
# participants affected / at risk	**22/36 (61.11%)**	**25/38 (65.79%)**	**23/32 (71.88%)**	**27/34 (79.41%)**
Cardiac disorders				
Angina pectoris [1]				
# participants affected / at risk	**2/36 (5.56%)**	**3/38 (7.89%)**	**4/32 (12.50%)**	**4/34 (11.76%)**
Bradycardia [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**3/34 (8.82%)**
Sinus bradycardia [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**2/32 (6.25%)**	**0/34 (0.00%)**
Ear and labyrinth disorders				
Vertigo [1]				
# participants affected / at risk	**0/36 (0.00%)**	**3/38 (7.89%)**	**2/32 (6.25%)**	**1/34 (2.94%)**
Gastrointestinal disorders				
Abdominal pain [1]				
# participants affected / at risk	**0/36 (0.00%)**	**2/38 (5.26%)**	**1/32 (3.13%)**	**0/34 (0.00%)**
Nausea [1]				
# participants affected / at risk	**1/36 (2.78%)**	**3/38 (7.89%)**	**3/32 (9.38%)**	**4/34 (11.76%)**
General disorders				
Catheter site haematoma [1]				
# participants affected / at risk	**12/36 (33.33%)**	**9/38 (23.68%)**	**9/32 (28.13%)**	**10/34 (29.41%)**
Catheter site haemorrhage [1]				
# participants affected / at risk	**3/36 (8.33%)**	**0/38 (0.00%)**	**3/32 (9.38%)**	**2/34 (5.88%)**
Catheter site pain [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**2/34 (5.88%)**
Chest pain [1]				
# participants affected / at risk	**0/36 (0.00%)**	**2/38 (5.26%)**	**1/32 (3.13%)**	**3/34 (8.82%)**
Pyrexia [1]				
# participants affected / at risk	**0/36 (0.00%)**	**0/38 (0.00%)**	**0/32 (0.00%)**	**2/34 (5.88%)**
Investigations				
Cardiac enzymes increased [1]				
# participants affected / at risk	**3/36 (8.33%)**	**1/38 (2.63%)**	**1/32 (3.13%)**	**0/34 (0.00%)**

Haematocrit decreased [1]				
# participants affected / at risk	0/36 (0.00%)	1/38 (2.63%)	1/32 (3.13%)	3/34 (8.82%)
Haemoglobin decreased [1]				
# participants affected / at risk	1/36 (2.78%)	1/38 (2.63%)	2/32 (6.25%)	3/34 (8.82%)
Red blood cell count decreased [1]				
# participants affected / at risk	0/36 (0.00%)	0/38 (0.00%)	1/32 (3.13%)	3/34 (8.82%)
Troponin T increased [1]				
# participants affected / at risk	2/36 (5.56%)	2/38 (5.26%)	0/32 (0.00%)	0/34 (0.00%)
Metabolism and nutrition disorders				
Hyperglycaemia [1]				
# participants affected / at risk	0/36 (0.00%)	0/38 (0.00%)	0/32 (0.00%)	2/34 (5.88%)
Hyponatraemia [1]				
# participants affected / at risk	0/36 (0.00%)	0/38 (0.00%)	2/32 (6.25%)	0/34 (0.00%)
Musculoskeletal and connective tissue disorders				
Arthralgia [1]				
# participants affected / at risk	1/36 (2.78%)	0/38 (0.00%)	0/32 (0.00%)	3/34 (8.82%)
Back pain [1]				
# participants affected / at risk	2/36 (5.56%)	1/38 (2.63%)	3/32 (9.38%)	4/34 (11.76%)
Pain in extremity [1]				
# participants affected / at risk	1/36 (2.78%)	2/38 (5.26%)	0/32 (0.00%)	0/34 (0.00%)
Nervous system disorders				
Headache [1]				
# participants affected / at risk	1/36 (2.78%)	1/38 (2.63%)	2/32 (6.25%)	0/34 (0.00%)
Syncope vasovagal [1]				
# participants affected / at risk	3/36 (8.33%)	1/38 (2.63%)	0/32 (0.00%)	1/34 (2.94%)
Psychiatric disorders				
Agitation [1]				
# participants affected / at risk	1/36 (2.78%)	0/38 (0.00%)	0/32 (0.00%)	2/34 (5.88%)
Respiratory, thoracic and mediastinal disorders				
Cough [1]				
# participants affected / at risk	1/36 (2.78%)	0/38 (0.00%)	2/32 (6.25%)	0/34 (0.00%)
Vascular disorders				
Hypertension [1]				
# participants affected / at risk	0/36 (0.00%)	4/38 (10.53%)	2/32 (6.25%)	5/34 (14.71%)
Hypotension [1]				
# participants affected / at risk	3/36 (8.33%)	2/38 (5.26%)	4/32 (12.50%)	5/34 (14.71%)

1 Term from vocabulary, MedDRA 9.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** No text entered.

Results Point of Contact:

Name/Title: Clinical Trials, Information Desk
Organization: Mitsubishi Tanabe Pharma Corporation
e-mail: cti-inq-ml@ml.mt-pharma.co.jp

Publications of Results:

Rössig L, Genth-Zotz S, Rau M, Heyndrickx GR, Schneider T, Gulba DC, Desaga M, Buerke M, Harder S, Zeiher AM; ARG-E04 study group. Argatroban for elective percutaneous coronary intervention: the ARG-E04 multi-center study. Int J Cardiol. 2011 Apr 14;148(2):214-9. doi: 10.1016/j.ijcard.2010.02.044. Epub 2010 Mar 11.

ClinicalTrials.gov Identifier: NCT00508924 History of Changes
Other Study ID Numbers: ARG-E04
Study First Received: July 26, 2007
Results First Received: November 6, 2012
Last Updated: November 6, 2012
Health Authority: Germany: Federal Institute for Drugs and Medical Devices