Efficacy and Safety Study of MCI-196 Versus Simvastatin for Dyslipidaemia in Chronic Kidney Disease (CKD) Subjects on Dialysis

This study has been completed.

Sponsor:
Mitsubishi Tanabe Pharma Corporation

Information provided by (Responsible Party):
Mitsubishi Tanabe Pharma Corporation

ClinicalTrials.gov Identifier:
NCT00858637

First received: March 9, 2009
Last updated: December 8, 2014
Last verified: December 2014
History of Changes

Results First Received: September 8, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Kidney Disease
Interventions:	Drug: MCI-196 Drug: Placebo of Simvastatin Drug: Simvastatin Drug: Placebo of MCI-196

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
MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	Active Comparison Phase: 3, 6, 9, 12g of MCI-196 / day as titrated • There was a gap of 1 subject between "STARTED" and "Overall Number of Baseline Participants". • One subject (A) was randomised to simvastatin (active) group but was dispensed MCI-196 in error at Week 12. This subject was counted as

	"STARTED" of Simvastatin (Active) group but counted as "Baseline Participants" of MCI-196 (active) group.
MCI-196 (Active) + Simvastin (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period
MCI-196 (Placebo) + Simvastin (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period
Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase	Active Comparison Phase: 10 mg to 40 mg of Simvastatin / day as titrated • There was a gap of 2 subject between "STARTED" and "Overall Number of Baseline Participants". • One subject did not take any study medication and excluded from "Baseline Participants". • In addition, one subject (A) was randomised to simvastatin (active) group but was dispensed MCI-196 in error at Week 12. This subject was counted as "STARTED" of Simvastatin (Active) group but counted as "Baseline Participants" of MCI-196 (active) group.
Simvastin (Active) + MCI-196 (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period
Simvastin (Placebo) + MCI-196 (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period

Participant Flow for 2 periods

Period 1: Active Comparison Phase

	MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	MCI-196 (Active) + Simvastin (Placebo)/ Withdrawal Phase	MCI-196 (Placebo) + Simvastin (Placebo)/ Withdrawal Phase	Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase	Simvastin (Active) + MCI-196 (Placebo)/ Withdrawal Phase	Simvastin (Placebo) + MCI-196 (Placebo)/ Withdrawal Phase
STARTED	**127**	**0**	**0**	**133**	**0**	**0**
COMPLETED	**103**	**0**	**0**	**115**	**0**	**0**
NOT COMPLETED	**24**	**0**	**0**	**18**	**0**	**0**
Adverse Event	**14**	**0**	**0**	**9**	**0**	**0**
Death	**1**	**0**	**0**	**1**	**0**	**0**
Physician Decision	**1**	**0**	**0**	**1**	**0**	**0**
Withdrawal by Subject	**7**	**0**	**0**	**6**	**0**	**0**
Other Reasons	**1**	**0**	**0**	**1**	**0**	**0**

Period 2: Placebo-controlled Withdrawal Phase

	MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	MCI-196 (Active) + Simvastin (Placebo)/ Withdrawal Phase	MCI-196 (Placebo) + Simvastin (Placebo)/ Withdrawal Phase	Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase	Simvastin (Active) + MCI-196 (Placebo)/ Withdrawal Phase	Simvastin (Placebo) + MCI-196 (Placebo)/ Withdrawal Phase
STARTED	**0**	**49**	**54**	**0**	**56**	**59**
	0	**49**	**53**	**0**	**55**	**58**

COMPLETED						
NOT COMPLETED	**0**	**0**	**1**	**0**	**1**	**1**
Death	**0**	**0**	**1**	**0**	**1**	**0**
Withdrawal by Subject	**0**	**0**	**0**	**0**	**0**	**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
MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	Active Comparison Phase: 3, 6, 9, 12g of MCI-196 / day as titrated • There was a gap of 1 subject between "STARTED" and "Overall Number of Baseline Participants". • One subject (A) was randomised to simvastatin (active) group but was dispensed MCI-196 in error at Week 12. This subject was counted as "STARTED" of Simvastatin (Active) group but counted as "Baseline Participants" of MCI-196 (active) group.
Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase	Active Comparison Phase: 10 mg to 40 mg of Simvastatin / day as titrated • There was a gap of 2 subject between "STARTED" and "Overall Number of Baseline Participants". • One subject did not take any study medication and excluded from "Baseline Participants". • In addition, one subject (A) was randomised to simvastatin (active) group but was dispensed MCI-196 in error at Week 12. This subject was counted as "STARTED" of Simvastatin (Active) group but counted as "Baseline Participants" of MCI-196 (active) group.
Total	Total of all reporting groups

Baseline Measures

	MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	**Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase**	**Total**
Number of Participants [units: participants]	**128**	**131**	**259**
Age [units: years] Mean (Standard Deviation)	**53.3 (14.1)**	**54.2 (13.6)**	**53.8 (13.8)**
Gender [units: participants]			
Female	**59**	**61**	**120**
Male	**69**	**70**	**139**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change in Serum LDL-cholesterol Levels From Week 16 to Week 20 (LOCF) (ITT2) [Time Frame: week20 minus week16]

Measure Type	Primary
Measure Title	Percent Change in Serum LDL-cholesterol Levels From Week 16 to Week 20 (LOCF) (ITT2)
Measure Description	Percent Change from Week 16 to Week 20 (LOCF)
Time Frame	week20 minus week16
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.
ITT2 population included all re-randomised subjects who completed 16 weeks in the active treatment groups (MCI-196 or simvastatin), received at least 1 dose of study medication in the Placebo-controlled withdrawal phase and had at least 1 central serum LDL-C value after Week 16.

Reporting Groups

	Description
MCI-196 (Active) + Simvastin (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period
MCI-196 (Placebo) + Simvastin (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period
Simvastin (Active) + MCI-196 (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period
Simvastin (Placebo) + MCI-196 (Placebo)/ Withdrawal Phase	Placebo-controlled Withdrawal Phase: dose level at the end of dose titration in the flexible dose period

Measured Values

	MCI-196 (Active) + Simvastin (Placebo)/ Withdrawal Phase	**MCI-196 (Placebo) + Simvastin (Placebo)/ Withdrawal Phase**	**Simvastin (Active) + MCI-196 (Placebo)/ Withdrawal Phase**	**Simvastin (Placebo) + MCI-196 (Placebo)/ Withdrawal Phase**
Number of Participants Analyzed [units: participants]	**49**	**53**	**55**	**58**
Percent Change in Serum LDL-cholesterol Levels From Week 16 to Week 20 (LOCF) (ITT2) [units: Percent Change of LDL-cholesterol] Mean (Standard Deviation)	**4.03 (19.92)**	**42.55 (30.96)**	**2.76 (18.43)**	**49.84 (41.89)**

No statistical analysis provided for Percent Change in Serum LDL-cholesterol Levels From Week 16 to Week 20 (LOCF) (ITT2)

2. Secondary: Percent Change in Serum LDL-cholesterol Levels From Baseline to Week 16 (LOCF) (ITT1) [Time Frame: week16 minus week0]

Measure Type	Secondary
Measure Title	Percent Change in Serum LDL-cholesterol Levels From Baseline to Week 16 (LOCF) (ITT1)
Measure Description	Percent Change from Baseline to Week 16 (LOCF)

Time Frame	week16 minus week0
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.
ITT1 population included all subjects who received a randomisation number, took at least 1 dose of study medication and had at least 1 central serum LDL-C value after the start of study medication.

Reporting Groups

	Description
MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	Active Comparison Phase: 3, 6, 9, 12g of MCI-196 / day as titrated
Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase	Active Comparison Phase: 10 mg to 40 mgof Simvastatin / day as titrated

Measured Values

	MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	**Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase**
Number of Participants Analyzed [units: participants]	**125**	**127**
Percent Change in Serum LDL-cholesterol Levels From Baseline to Week 16 (LOCF) (ITT1) [units: Percent Change of LDL-cholesterol] Mean (Standard Deviation)	**-25.67 (19.45)**	**-26.38 (22.9)**

No statistical analysis provided for Percent Change in Serum LDL-cholesterol Levels From Baseline to Week 16 (LOCF) (ITT1)

3. Secondary: Change in Phosphorus(P), Calcium(Ca), Calcium-phosphorus Ion Product(PxCa) and Parathyroid Hormone (PTH) [Time Frame: 16 weeks and 20 weeks]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

4. Secondary: Vital Signs, Adverse Events, and Laboratory Values [Time Frame: throughout study]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** Yes

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	16 weeks (Baseline - 16 weeks)
Additional Description	Baseline Characteristics are reported based on the safety population, which is the actual number of participants that received each intervention. Details are described in [Arm/Group Description] of [Baseline Characteristics]

Reporting Groups

	Description
MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	Active Comparison Phase: 3, 6, 9, 12g of MCI-196 / day as titrated
Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase	Active Comparison Phase: 10 mg to 40 mg of Simvastatin / day as titrated

Serious Adverse Events

	MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	**Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase**

Total, serious adverse events		
# participants affected / at risk	**16/128 (12.50%)**	**12/131 (9.16%)**
Blood and lymphatic system disorders		
Anaemia		
# participants affected / at risk	**0/128 (0.00%)**	**2/131 (1.53%)**
Cardiac disorders		
Angina unstable		
# participants affected / at risk	**1/128 (0.78%)**	**1/131 (0.76%)**
Cardiac arrest		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Gastrointestinal disorders		
Abdominal pain upper		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Gastritis erosive		
# participants affected / at risk	**0/128 (0.00%)**	**1/131 (0.76%)**
Inguinal hernia		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Nausea		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Peritonitis		
# participants affected / at risk	**1/128 (0.78%)**	**3/131 (2.29%)**
General disorders		
Pyrexia		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Hepatobiliary disorders		
Cholecystitis acute		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Immune system disorders		
Hypersensitivity		
# participants affected / at risk	**0/128 (0.00%)**	**1/131 (0.76%)**
Infections and infestations		
Gangrene		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Pneumonia		
# participants affected / at risk	**2/128 (1.56%)**	**0/131 (0.00%)**
Postoperative wound infection		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Salmonella sepsis		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Upper respiratory tract infection		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Urinary tract infection		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Injury, poisoning and procedural complications		
Arteriovenous fistula thrombosis		

# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Haemodialysis-induced symptom		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Hip fracture		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Peritoneal dialysis complication		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Vascular pseudoaneurysm		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Musculoskeletal and connective tissue disorders		
Back pain		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Muscle spasms		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Endometrial cancer		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Parathyroid tumour benign		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Renal cancer		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Nervous system disorders		
Cerebral haemorrhage		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Cerebrovascular accident		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Syncope		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)

Other Adverse Events

Hide Other Adverse Events

Time Frame	16 weeks (Baseline - 16 weeks)
Additional Description	Baseline Characteristics are reported based on the safety population, which is the actual number of participants that received each intervention. Details are described in [Arm/Group Description] of [Baseline Characteristics]

Frequency Threshold

Threshold above which other adverse events are reported	0

Reporting Groups

	Description
MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	Active Comparison Phase: 3, 6, 9, 12g of MCI-196 / day as titrated
Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase	Active Comparison Phase: 10 mg to 40 mg of Simvastatin / day as titrated

Other Adverse Events

	MCI-196 (Active) + Simvastatin (Placebo)/ Comparison Phase	Simvastatin (Active) + MCI-196 (Placebo)/ Comparion Phase
Total, other (not including serious) adverse events		
# participants affected / at risk	89/128 (69.53%)	87/131 (66.41%)
Blood and lymphatic system disorders		
Anaemia		
# participants affected / at risk	11/128 (8.59%)	12/131 (9.16%)
Anaemia vitamin B12 deficiency		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Leukocytosis		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Nephrogenic anaemia		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Cardiac disorders		
Angina pectoris		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Angina unstable		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Aortic valve calcification		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Atrioventricular block second degree		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Bradycardia		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Coronary artery stenosis		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Left ventricular hypertrophy		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Palpitations		
# participants affected / at risk	2/128 (1.56%)	2/131 (1.53%)
Sinus tachycardia		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Ear and labyrinth disorders		
Vertigo		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Endocrine disorders		
Hyperparathyroidism secondary		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Eye disorders		
Eye haemorrhage		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Eyelid oedema		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)

Gastrointestinal disorders		
Abdominal discomfort		
# participants affected / at risk	**5/128 (3.91%)**	**5/131 (3.82%)**
Abdominal distension		
# participants affected / at risk	**0/128 (0.00%)**	**2/131 (1.53%)**
Abdominal pain		
# participants affected / at risk	**3/128 (2.34%)**	**3/131 (2.29%)**
Abdominal pain upper		
# participants affected / at risk	**2/128 (1.56%)**	**5/131 (3.82%)**
Aerophagia		
# participants affected / at risk	**0/128 (0.00%)**	**1/131 (0.76%)**
Constipation		
# participants affected / at risk	**6/128 (4.69%)**	**8/131 (6.11%)**
Diarrhoea		
# participants affected / at risk	**4/128 (3.13%)**	**5/131 (3.82%)**
Dry mouth		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Dyspepsia		
# participants affected / at risk	**10/128 (7.81%)**	**7/131 (5.34%)**
Dysphagia		
# participants affected / at risk	**2/128 (1.56%)**	**0/131 (0.00%)**
Enterocolitis		
# participants affected / at risk	**0/128 (0.00%)**	**1/131 (0.76%)**
Flatulence		
# participants affected / at risk	**3/128 (2.34%)**	**2/131 (1.53%)**
Gastric disorder		
# participants affected / at risk	**2/128 (1.56%)**	**1/131 (0.76%)**
Gastric ulcer		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Gastritis		
# participants affected / at risk	**2/128 (1.56%)**	**1/131 (0.76%)**
Hyperchlorhydria		
# participants affected / at risk	**2/128 (1.56%)**	**0/131 (0.00%)**
Infrequent bowel movements		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Inguinal hernia		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Nausea		
# participants affected / at risk	**8/128 (6.25%)**	**12/131 (9.16%)**
Peptic ulcer		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Peritonitis		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Stomatitis		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Vomiting		

# participants affected / at risk	2/128 (1.56%)	4/131 (3.05%)
General disorders		
Asthenia		
# participants affected / at risk	2/128 (1.56%)	3/131 (2.29%)
Chest pain		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Hyperthermia		
# participants affected / at risk	2/128 (1.56%)	0/131 (0.00%)
Non-cardiac chest pain		
# participants affected / at risk	0/128 (0.00%)	2/131 (1.53%)
Oedema peripheral		
# participants affected / at risk	4/128 (3.13%)	2/131 (1.53%)
Pyrexia		
# participants affected / at risk	0/128 (0.00%)	3/131 (2.29%)
Hepatobiliary disorders		
Hepatic pain		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Immune system disorders		
Allergy to arthropod sting		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Infections and infestations		
Bronchitis		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Diabetic foot infection		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Endocarditis		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Gastroenteritis		
# participants affected / at risk	2/128 (1.56%)	1/131 (0.76%)
Influenza		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Lymph node tuberculosis		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Nasopharyngitis		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Pulpitis dental		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Respiratory tract infection		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Respiratory tract infection viral		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Rhinitis		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Staphylococcal bacteraemia		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Tonsillitis		

# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Upper respiratory tract infection		
# participants affected / at risk	3/128 (2.34%)	4/131 (3.05%)
Urinary tract infection		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Injury, poisoning and procedural complications		
Arteriovenous fistula site complication		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Arteriovenous fistula site haemorrhage		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Arteriovenous fistula thrombosis		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Haemodialysis-induced symptom		
# participants affected / at risk	2/128 (1.56%)	7/131 (5.34%)
Joint dislocation		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Post procedural constipation		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Procedural hypertension		
# participants affected / at risk	5/128 (3.91%)	5/131 (3.82%)
Procedural hypotension		
# participants affected / at risk	5/128 (3.91%)	8/131 (6.11%)
Procedural pain		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Thrombosis in device		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Traumatic haemorrhage		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Ulna fracture		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Investigations		
Alanine aminotransferase increased		
# participants affected / at risk	0/128 (0.00%)	2/131 (1.53%)
Aspartate aminotransferase increased		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Blood alkaline phosphatase increased		
# participants affected / at risk	2/128 (1.56%)	1/131 (0.76%)
Blood creatinine increased		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Blood parathyroid hormone increased		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Blood phosphorus increased		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Blood urea increased		

# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Body temperature increased		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Eosinophil count increased		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Gamma-glutamyltransferase increased		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Haemoglobin decreased		
# participants affected / at risk	0/128 (0.00%)	2/131 (1.53%)
Lipids increased		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Weight decreased		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Metabolism and nutrition disorders		
Decreased appetite		
# participants affected / at risk	3/128 (2.34%)	1/131 (0.76%)
Dehydration		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Diabetes mellitus		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Hypercalcaemia		
# participants affected / at risk	1/128 (0.78%)	2/131 (1.53%)
Hyperkalaemia		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Hyperphosphataemia		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Hypertriglyceridaemia		
# participants affected / at risk	2/128 (1.56%)	0/131 (0.00%)
Hypoglycaemia		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Hypokalaemia		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Iron deficiency		
# participants affected / at risk	0/128 (0.00%)	2/131 (1.53%)
Musculoskeletal and connective tissue disorders		
Arthralgia		
# participants affected / at risk	2/128 (1.56%)	4/131 (3.05%)
Back pain		
# participants affected / at risk	1/128 (0.78%)	2/131 (1.53%)
Bone pain		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Gouty arthritis		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Muscle spasms		
# participants affected / at risk	3/128 (2.34%)	4/131 (3.05%)

Musculoskeletal pain		
# participants affected / at risk	2/128 (1.56%)	0/131 (0.00%)
Myalgia		
# participants affected / at risk	1/128 (0.78%)	5/131 (3.82%)
Pain in extremity		
# participants affected / at risk	2/128 (1.56%)	1/131 (0.76%)
Periarthritis		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Nervous system disorders		
Dizziness		
# participants affected / at risk	0/128 (0.00%)	2/131 (1.53%)
Headache		
# participants affected / at risk	12/128 (9.38%)	6/131 (4.58%)
Paraesthesia		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Restless legs syndrome		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Speech disorder		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Syncope		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Tonic convulsion		
# participants affected / at risk	2/128 (1.56%)	1/131 (0.76%)
Psychiatric disorders		
Anxiety		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Insomnia		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Stress		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Renal and urinary disorders		
Renal failure		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Renal tubular acidosis		
# participants affected / at risk	1/128 (0.78%)	1/131 (0.76%)
Respiratory, thoracic and mediastinal disorders		
Cough		
# participants affected / at risk	2/128 (1.56%)	1/131 (0.76%)
Dyspnoea		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Pleural effusion		
# participants affected / at risk	1/128 (0.78%)	0/131 (0.00%)
Rhinitis allergic		
# participants affected / at risk	0/128 (0.00%)	1/131 (0.76%)
Skin and subcutaneous tissue disorders		

Blister		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Hyperhidrosis		
# participants affected / at risk	**0/128 (0.00%)**	**1/131 (0.76%)**
Pruritus		
# participants affected / at risk	**2/128 (1.56%)**	**1/131 (0.76%)**
Rash papular		
# participants affected / at risk	**0/128 (0.00%)**	**1/131 (0.76%)**
Surgical and medical procedures		
Hospitalisation		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Vascular disorders		
Hypertension		
# participants affected / at risk	**6/128 (4.69%)**	**8/131 (6.11%)**
Hypertensive crisis		
# participants affected / at risk	**2/128 (1.56%)**	**1/131 (0.76%)**
Hypotension		
# participants affected / at risk	**10/128 (7.81%)**	**9/131 (6.87%)**
Phlebitis		
# participants affected / at risk	**1/128 (0.78%)**	**0/131 (0.00%)**
Thrombophlebitis		
# participants affected / at risk	**0/128 (0.00%)**	**1/131 (0.76%)**

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

Responsible Party:	Mitsubishi Tanabe Pharma Corporation
ClinicalTrials.gov Identifier:	NCT00858637 History of Changes
Other Study ID Numbers:	MCI-196-E11
Study First Received:	March 9, 2009
Results First Received:	September 8, 2014
Last Updated:	December 8, 2014
Health Authority:	Singapore: Health Sciences Authority Belarus: Ministry of Health Malaysia: Ministry of Health Bulgaria: Ministry of Health Croatia: Ministry of Health and Social Care Denmark: Danish Medicines Agency Indonesia: National Agency of Drug and Food Control Israel: Ministry of Health Latvia: State Agency of Medicines Lithuania: State Medicine Control Agency - Ministry of Health Romania: Ministry of Public Health Thailand: Food and Drug Administration