Trial record **1 of 2** for: NCT00416520
Previous Study | Return to List | Next Study

A Phase III, Multicentre, Double-Blind, Placebo-Controlled Withdrawal Study in Patients With Hyperphosphatemia

This study has been completed.

Sponsor:
Mitsubishi Tanabe Pharma Corporation

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

ClinicalTrials.gov Identifier:
NCT00416520

First received: December 27, 2006
Last updated: October 28, 2014
Last verified: October 2014
History of Changes

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

Results First Received: August 22, 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
Conditions:	Chronic Kidney Disease Hyperphosphatemia
Interventions:	Drug: MCI-196 (Colestilan(INN), Colestimide(JAN), CHOLEBINE®) Drug: Placebo Drug: Another phosphate binder (Sevelamer)

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 (Open-label Period)	3, 6, 9, 12, or 15g/day as titrated • There was a gap of 3 subjects between "STARTED" and "Overall Number of Baseline Participants". • Two subjects were randomised to receive MCI-196, but did not take study medication. These 2 subjects were excluded from "Baseline Participants" of MCI-196 group.

	• In addition, one subject (A) was randomised to receive MCI-196, but took sevelamer instead. This subject was counted as MCI-196 group for "STARTED" but counted as Sevelamer group for "Baseline Participants".
Sevelamer (Open-label Period)	2.4, 4.8, 7.2, 9.6, or 12.0g/day as titrated • There was a gap of 2 subjects between "STARTED" and "Overall Number of Baseline Participants". • Three subjects in Sevelamer group were randomised in error and did not take any study medication. These 3 subjects were excluded from "Baseline Participants" of Sevelamer group. • However, one subject (A) was randomised to receive MCI-196, but took sevelamer instead. This subject was counted as MCI-196 group for "STARTED" but counted as Sevelamer group for "Baseline Participants".
MCI-196 (Placebo-controlled Withdrawal Period)	dose level at the end of dose titration in the flexible dose period
Placebo (Placebo-controlled Withdrawal Period)	dose level at the end of dose titration in the flexible dose period There was a gap of 1 subject between "STARTED" and "Overall Number of Baseline Participants" One subject did not take any study medication and excluded from "Baseline Participants".

Participant Flow for 2 periods

Period 1: Open-label Period

	MCI-196 (Open-label Period)	Sevelamer (Open-label Period)	MCI-196 (Placebo-controlled Withdrawal Period)	Placebo (Placebo-controlled Withdrawal Period)
STARTED	**165**	**171**	**0**	**0**
COMPLETED	**105**	**139**	**0**	**0**
NOT COMPLETED	**60**	**32**	**0**	**0**
Adverse Event	**28**	**10**	**0**	**0**
Death	**2**	**1**	**0**	**0**
Lack of Efficacy	**8**	**1**	**0**	**0**
Protocol Violation	**3**	**3**	**0**	**0**
Withdrawal by Subject	**16**	**5**	**0**	**0**
Other Reasons	**3**	**12**	**0**	**0**

Period 2: Placebo-controlled Withdrawal Period

	MCI-196 (Open-label Period)	Sevelamer (Open-label Period)	MCI-196 (Placebo-controlled Withdrawal Period)	Placebo (Placebo-controlled Withdrawal Period)
STARTED	**0**	**0**	**50**	**54**
COMPLETED	**0**	**0**	**49**	**49**
NOT COMPLETED	**0**	**0**	**1**	**5**
Adverse Event	**0**	**0**	**0**	**1**
Lack of Efficacy	**0**	**0**	**0**	**3**
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
MCI-196 (Open-label Period)	No text entered.
Sevelamer (Open-label Period)	No text entered.
Total	Total of all reporting groups

Baseline Measures

	MCI-196 (Open-label Period)	**Sevelamer (Open-label Period)**	**Total**
Number of Participants [units: participants]	**162**	**169**	**331**
Age [units: years] Mean (Standard Deviation)	**56.4 (14.7)**	**59.5 (13.8)**	**58.0 (14.3)**
Gender [units: participants]			
Female	**54**	**72**	**126**
Male	**108**	**97**	**205**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Serum Phosphorus Levels From Week 12 to Week 16 (LOCF) (ITT2) [Time Frame: week16 minus week12]

Measure Type	Primary
Measure Title	Change in Serum Phosphorus Levels From Week 12 to Week 16 (LOCF) (ITT2)
Measure Description	ITT2 population included all re-randomised subjects who completed 12 weeks in the MCI-196 treatment group and received at least 1 dose of study medication in the placebo-controlled withdrawal period and had at least 1 central serum phosphorus value after 12 weeks.
Time Frame	week16 minus week12
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 12 weeks in the MCI-196 treatment group and received at least 1 dose of study medication in the placebo-controlled withdrawal period and had at least 1 central serum phosphorus value after 12 weeks.

Reporting Groups

	Description
MCI-196 (Placebo-controlled Withdrawal Period)	dose level at the end of dose titration in the flexible dose period
Placebo (Placebo-controlled Withdrawal Period)	dose level at the end of dose titration in the flexible dose period

Measured Values

	MCI-196 (Placebo-controlled Withdrawal Period)	Placebo (Placebo-controlled Withdrawal Period)
Number of Participants Analyzed [units: participants]	**50**	**53**
Change in Serum Phosphorus Levels From Week 12 to Week 16 (LOCF) (ITT2) [units: mg / dL] Mean (Standard Deviation)	**-0.24 (1.46)**	**1.27 (1.48)**

No statistical analysis provided for Change in Serum Phosphorus Levels From Week 12 to Week 16 (LOCF) (ITT2)

2. Secondary: Change in Serum Phosphorus Levels From Baseline to Week 12 (LOCF) (ITT1) [Time Frame: week12 minus week0]

Measure Type	Secondary
Measure Title	Change in Serum Phosphorus Levels From Baseline to Week 12 (LOCF) (ITT1)
Measure Description	ITT1 population included all subjects who received a randomisation number (at Week 0), took at least 1 dose of study medication and had at least 1 central serum phosphorus value after the start of study medication.
Time Frame	week12 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 (at Week 0), took at least 1 dose of study medication and had at least 1 central serum phosphorus value after the start of study medication.

Reporting Groups

	Description
MCI-196 (Open-label Period)	3, 6, 9, 12, or 15g/day as titrated
Sevelamer (Open-label Period)	2.4, 4.8, 7.2, 9.6, or 12.0g/day as titrated

Measured Values

	MCI-196 (Open-label Period)	Sevelamer (Open-label Period)
Number of Participants Analyzed [units: participants]	**160**	**167**
Change in Serum Phosphorus Levels From Baseline to Week 12 (LOCF) (ITT1) [units: mg / dL] Mean (Standard Deviation)	**-1.12 (1.63)**	**-2.16 (1.55)**

No statistical analysis provided for Change in Serum Phosphorus Levels From Baseline to Week 12 (LOCF) (ITT1)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
MCI-196 (Open-label Period)	3, 6, 9, 12, or 15g/day as titrated
Sevelamer (Open-label Period)	2.4, 4.8, 7.2, 9.6, or 12.0g/day as titrated
MCI-196 (Placebo-Controlled Period)	dose level at the end of dose titration in the flexible dose period
Placebo (Placebo-Controlled Period)	dose level at the end of dose titration in the flexible dose period

Serious Adverse Events

	MCI-196 (Open-label Period)	Sevelamer (Open-label Period)	MCI-196 (Placebo-Controlled Period)	Placebo (Placebo-Controlled Period)
Total, serious adverse events				
# participants affected / at risk	**26/162 (16.05%)**	**25/169 (14.79%)**	**2/50 (4.00%)**	**3/53 (5.66%)**
Blood and lymphatic system disorders				
Anaemia				
# participants affected / at risk	**2/162 (1.23%)**	**1/169 (0.59%)**	**0/50 (0.00%)**	**1/53 (1.89%)**
Cardiac disorders				
Acute coronary syndrome				
# participants affected / at risk	**1/162 (0.62%)**	**0/169 (0.00%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Angina pectoris				
# participants affected / at risk	**1/162 (0.62%)**	**1/169 (0.59%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Atrial fibrillation				
# participants affected / at risk	**1/162 (0.62%)**	**0/169 (0.00%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Atrioventricular block complete				
# participants affected / at risk	**0/162 (0.00%)**	**2/169 (1.18%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Cardiac arrest				
# participants affected / at risk	**0/162 (0.00%)**	**1/169 (0.59%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Cardiovascular insufficiency				
# participants affected / at risk	**0/162 (0.00%)**	**1/169 (0.59%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Congestive cardiomyopathy				
# participants affected / at risk	**0/162 (0.00%)**	**1/169 (0.59%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Coronary artery disease				

# participants affected / at risk	1/162 (0.62%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Coronary artery insufficiency				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Coronary artery stenosis				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Ischaemic cardiomyopathy				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Myocardial infarction				
# participants affected / at risk	3/162 (1.85%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Gastrointestinal disorders				
Diverticulum intestinal				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Duodenal ulcer haemorrhage				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Haemorrhoids				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Nausea				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Peritonitis				
# participants affected / at risk	1/162 (0.62%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Vomiting				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
General disorders				
Hernia				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Impaired healing				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Pyrexia				
# participants affected / at risk	1/162 (0.62%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Hepatobiliary disorders				
Biliary colic				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Cholelithiasis				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Immune system disorders				

Anaphylactic reaction				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Infections and infestations				
Bronchopneumonia				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	1/50 (2.00%)	0/53 (0.00%)
Catheter sepsis				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Cellulitis				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Diverticulitis				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Fungal infection				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Pyelonephritis acute				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Septic shock				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Urinary tract infection				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Pneumonia				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	1/50 (2.00%)	0/53 (0.00%)
Injury, poisoning and procedural complications				
Arteriovenous fistula site complication				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Arteriovenous fistula site haemorrhage				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Arteriovenous fistula thrombosis				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Dialysis device complication				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Investigations				
Arteriogram coronary				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	1/53 (1.89%)

Hepatic enzyme increased				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Metabolism and nutrition disorders				
Fluid overload				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Fluid retention				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Nervous system disorders				
Carotid artery stenosis				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Cerebrovascular disorder				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Genital haemorrhage				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Testicular pain				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Dyspnoea				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Epistaxis				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Respiratory distress				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	1/50 (2.00%)	0/53 (0.00%)
Surgical and medical procedures				
Cataract operation				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Coronary arterial stent insertion				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)

Renal transplant				
# participants affected / at risk	1/162 (0.62%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Toe amputation				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Vascular disorders				
Circulatory collapse				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Hypovolaemic shock				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Peripheral vascular disorder				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)

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	1

Reporting Groups

	Description
MCI-196 (Open-label Period)	3, 6, 9, 12, or 15g/day as titrated
Sevelamer (Open-label Period)	2.4, 4.8, 7.2, 9.6, or 12.0g/day as titrated
MCI-196 (Placebo-Controlled Period)	dose level at the end of dose titration in the flexible dose period
Placebo (Placebo-Controlled Period)	dose level at the end of dose titration in the flexible dose period

Other Adverse Events

	MCI-196 (Open-label Period)	Sevelamer (Open-label Period)	MCI-196 (Placebo-Controlled Period)	Placebo (Placebo-Controlled Period)
Total, other (not including serious) adverse events				
# participants affected / at risk	126/162 (77.78%)	113/169 (66.86%)	20/50 (40.00%)	23/53 (43.40%)
Blood and lymphatic system disorders				
Anaemia				
# participants affected / at risk	6/162 (3.70%)	6/169 (3.55%)	0/50 (0.00%)	2/53 (3.77%)
Lymphadenopathy				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	1/50 (2.00%)	0/53 (0.00%)

Spontaneous haematoma				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Cardiac disorders				
Angina pectoris				
# participants affected / at risk	2/162 (1.23%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Cardiac failure				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	1/50 (2.00%)	0/53 (0.00%)
Sinus bradycardia				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	1/50 (2.00%)	0/53 (0.00%)
Endocrine disorders				
Hyperparathyroidism				
# participants affected / at risk	2/162 (1.23%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Hyperparathyroidism secondary				
# participants affected / at risk	2/162 (1.23%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Eye disorders				
Eye haemorrhage				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Gastrointestinal disorders				
Abdominal distension				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Abdominal pain				
# participants affected / at risk	8/162 (4.94%)	4/169 (2.37%)	0/50 (0.00%)	0/53 (0.00%)
Abdominal pain upper				
# participants affected / at risk	10/162 (6.17%)	8/169 (4.73%)	1/50 (2.00%)	0/53 (0.00%)
Constipation				
# participants affected / at risk	13/162 (8.02%)	11/169 (6.51%)	2/50 (4.00%)	0/53 (0.00%)
Diarrhoea				
# participants affected / at risk	21/162 (12.96%)	16/169 (9.47%)	2/50 (4.00%)	1/53 (1.89%)
Duodenitis				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Dyspepsia				
# participants affected / at risk	13/162 (8.02%)	6/169 (3.55%)	0/50 (0.00%)	1/53 (1.89%)
Eructation				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Faeces discoloured				

# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Flatulence				
# participants affected / at risk	4/162 (2.47%)	2/169 (1.18%)	0/50 (0.00%)	1/53 (1.89%)
Frequent bowel movements				
# participants affected / at risk	3/162 (1.85%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Gastritis				
# participants affected / at risk	2/162 (1.23%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Haemorrhoids				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Nausea				
# participants affected / at risk	15/162 (9.26%)	12/169 (7.10%)	0/50 (0.00%)	1/53 (1.89%)
Vomiting				
# participants affected / at risk	27/162 (16.67%)	9/169 (5.33%)	1/50 (2.00%)	0/53 (0.00%)
Toothache				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	1/50 (2.00%)	0/53 (0.00%)
General disorders				
Asthenia				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Catheter site erythema				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Catheter site pain				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Chest pain				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Fatigue				
# participants affected / at risk	2/162 (1.23%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Non-cardiac chest pain				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Oedema peripheral				
# participants affected / at risk	2/162 (1.23%)	1/169 (0.59%)	2/50 (4.00%)	0/53 (0.00%)
Pyrexia				
# participants affected / at risk	5/162 (3.09%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Infections and infestations				
Bronchitis				
# participants affected / at risk	5/162 (3.09%)	3/169 (1.78%)	2/50 (4.00%)	1/53 (1.89%)

Bronchopneumonia				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Cellulitis				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Cystitis				
# participants affected / at risk	0/162 (0.00%)	3/169 (1.78%)	0/50 (0.00%)	0/53 (0.00%)
Gastroenteritis				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	1/50 (2.00%)	0/53 (0.00%)
Influenza				
# participants affected / at risk	1/162 (0.62%)	4/169 (2.37%)	0/50 (0.00%)	0/53 (0.00%)
Nasopharyngitis				
# participants affected / at risk	8/162 (4.94%)	7/169 (4.14%)	0/50 (0.00%)	0/53 (0.00%)
Pharyngitis				
# participants affected / at risk	1/162 (0.62%)	5/169 (2.96%)	0/50 (0.00%)	0/53 (0.00%)
Respiratory tract infection				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Upper respiratory tract infection				
# participants affected / at risk	4/162 (2.47%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Urinary tract infection				
# participants affected / at risk	2/162 (1.23%)	1/169 (0.59%)	0/50 (0.00%)	0/53 (0.00%)
Bacteraemia				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Catheter site infection				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Rhinitis				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	2/50 (4.00%)	0/53 (0.00%)
Tonsillitis				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	1/50 (2.00%)	0/53 (0.00%)
Injury, poisoning and procedural complications				
Arteriovenous fistula site complication				
# participants affected / at risk	4/162 (2.47%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Arteriovenous fistula thrombosis				
# participants affected / at risk	2/162 (1.23%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)

Haemodialysis-induced symptom				
# participants affected / at risk	6/162 (3.70%)	9/169 (5.33%)	3/50 (6.00%)	0/53 (0.00%)
Limb injury				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Procedural hypertension				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Procedural hypotension				
# participants affected / at risk	3/162 (1.85%)	7/169 (4.14%)	0/50 (0.00%)	0/53 (0.00%)
Arteriovenous fistula site haemorrhage				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Eschar				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Investigations				
Blood parathyroid hormone increased				
# participants affected / at risk	1/162 (0.62%)	3/169 (1.78%)	1/50 (2.00%)	0/53 (0.00%)
C-reactive protein increased				
# participants affected / at risk	2/162 (1.23%)	2/169 (1.18%)	1/50 (2.00%)	1/53 (1.89%)
Electrocardiogram QT interval abnormal				
# participants affected / at risk	3/162 (1.85%)	0/169 (0.00%)	1/50 (2.00%)	0/53 (0.00%)
Haemoglobin decreased				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Blood phosphorus decreased				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Gamma-glutamyltransferase increased				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Vitamin D decreased				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Weight increased				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Metabolism and nutrition disorders				
Decreased appetite				
# participants affected / at risk	3/162 (1.85%)	3/169 (1.78%)	0/50 (0.00%)	0/53 (0.00%)

Fluid overload				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	1/53 (1.89%)
Fluid retention				
# participants affected / at risk	2/162 (1.23%)	1/169 (0.59%)	2/50 (4.00%)	0/53 (0.00%)
Hyperkalaemia				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	1/50 (2.00%)	0/53 (0.00%)
Hyperphosphataemia				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	1/50 (2.00%)	0/53 (0.00%)
Hypocalcaemia				
# participants affected / at risk	8/162 (4.94%)	6/169 (3.55%)	1/50 (2.00%)	0/53 (0.00%)
Hypoglycaemia				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	2/50 (4.00%)	0/53 (0.00%)
Acidosis				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Metabolic acidosis				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Musculoskeletal and connective tissue disorders				
Arthralgia				
# participants affected / at risk	5/162 (3.09%)	4/169 (2.37%)	1/50 (2.00%)	1/53 (1.89%)
Back pain				
# participants affected / at risk	5/162 (3.09%)	4/169 (2.37%)	1/50 (2.00%)	0/53 (0.00%)
Muscle spasms				
# participants affected / at risk	5/162 (3.09%)	1/169 (0.59%)	1/50 (2.00%)	1/53 (1.89%)
Musculoskeletal pain				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Pain in extremity				
# participants affected / at risk	5/162 (3.09%)	5/169 (2.96%)	1/50 (2.00%)	0/53 (0.00%)
Cervical spinal stenosis				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Osteoarthritis				
# participants affected / at risk	1/162 (0.62%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Osteonecrosis				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Nervous system disorders				
Headache				

# participants affected / at risk	6/162 (3.70%)	5/169 (2.96%)	1/50 (2.00%)	1/53 (1.89%)
Hypotonia				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Restless legs syndrome				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Psychiatric disorders				
Anxiety				
# participants affected / at risk	2/162 (1.23%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Insomnia				
# participants affected / at risk	1/162 (0.62%)	2/169 (1.18%)	0/50 (0.00%)	2/53 (3.77%)
Sleep disorder				
# participants affected / at risk	2/162 (1.23%)	0/169 (0.00%)	0/50 (0.00%)	0/53 (0.00%)
Renal and urinary disorders				
Haematuria				
# participants affected / at risk	1/162 (0.62%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Respiratory, thoracic and mediastinal disorders				
Cough				
# participants affected / at risk	5/162 (3.09%)	5/169 (2.96%)	0/50 (0.00%)	0/53 (0.00%)
Dyspnoea				
# participants affected / at risk	3/162 (1.85%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Oropharyngeal pain				
# participants affected / at risk	1/162 (0.62%)	3/169 (1.78%)	1/50 (2.00%)	0/53 (0.00%)
Pleural effusion				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Chronic obstructive pulmonary disease				
# participants affected / at risk	0/162 (0.00%)	1/169 (0.59%)	0/50 (0.00%)	1/53 (1.89%)
Pharyngeal erythema				
# participants affected / at risk	0/162 (0.00%)	0/169 (0.00%)	0/50 (0.00%)	1/53 (1.89%)
Skin and subcutaneous tissue disorders				
Eczema				
# participants affected / at risk	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)
Erythema				
	0/162 (0.00%)	2/169 (1.18%)	0/50 (0.00%)	0/53 (0.00%)

# participants affected / at risk				
Pruritus				
# participants affected / at risk	**5/162 (3.09%)**	**5/169 (2.96%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Skin ulcer				
# participants affected / at risk	**1/162 (0.62%)**	**2/169 (1.18%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Dry skin				
# participants affected / at risk	**0/162 (0.00%)**	**0/169 (0.00%)**	**0/50 (0.00%)**	**1/53 (1.89%)**
Surgical and medical procedures				
Renal transplant				
# participants affected / at risk	**2/162 (1.23%)**	**4/169 (2.37%)**	**0/50 (0.00%)**	**0/53 (0.00%)**
Vascular disorders				
Hypertension				
# participants affected / at risk	**12/162 (7.41%)**	**12/169 (7.10%)**	**1/50 (2.00%)**	**1/53 (1.89%)**
Hypotension				
# participants affected / at risk	**1/162 (0.62%)**	**6/169 (3.55%)**	**0/50 (0.00%)**	**1/53 (1.89%)**

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:

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Responsible Party:	Mitsubishi Tanabe Pharma Corporation
ClinicalTrials.gov Identifier:	NCT00416520 History of Changes
Other Study ID Numbers:	MCI-196-E07
Study First Received:	December 27, 2006
Results First Received:	August 22, 2014
Last Updated:	October 28, 2014
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency Italy: Ethics Committee Austria: Agency for Health and Food Safety Czech Republic: State Institute for Drug Control France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products South Africa: Medicines Control Council Spain: Ministry of Health and Consumption