Trial record **1 of 1** for: NCT00542815
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A Study of MCI-196 in Chronic Kidney Disease Stage V Subjects on Dialysis With Hyperphosphatemia

This study has been completed.

Sponsor:
Mitsubishi Tanabe Pharma Corporation

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

ClinicalTrials.gov Identifier:
NCT00542815

First received: October 10, 2007
Last updated: September 24, 2014
Last verified: September 2014
History of Changes

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

Results First Received: September 16, 2014

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Chronic Kidney Disease Dialysis Hyperphosphatemia
Interventions:	Drug: MCI-196 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 From E07 / E08 Studies	3, 6, 9, 12, or 15g / day as titrated
MCI-196 From E07 Study	3, 6, 9, 12, or 15g / day as titrated
Sevelamer From E07 Study	2.4, 4.8, 7.2, 9.6, or 12.0g / day as titrated

Participant Flow: Overall Study

	MCI-196 From E07 / E08 Studies	MCI-196 From E07 Study	Sevelamer From E07 Study

STARTED	**432**	**76**	**124**
COMPLETED	**326**	**44**	**92**
NOT COMPLETED	**106**	**32**	**32**
Adverse Event	**19**	**6**	**9**
Death	**10**	**7**	**3**
Lack of Efficacy	**9**	**2**	**0**
Physician Decision	**2**	**1**	**0**
Protocol Violation	**1**	**1**	**2**
Withdrawal by Subject	**41**	**5**	**8**
Other reasons	**24**	**10**	**10**

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 From E07 / E08 Studies	3, 6, 9, 12, or 15g / day as titrated
MCI-196 From E07 Study	3, 6, 9, 12, or 15g / day as titrated
Sevelamer From E07 Study	2.4, 4.8, 7.2, 9.6, or 12.0g / day as titrated
Total	Total of all reporting groups

Baseline Measures

	MCI-196 From E07 / E08 Studies	MCI-196 From E07 Study	Sevelamer From E07 Study	Total
Number of Participants [units: participants]	**432**	**76**	**124**	**632**
Age, Customized [units: participants]				
<65 years	**374**	**55**	**77**	**506**
>=65 years	**58**	**21**	**47**	**126**
Gender [units: participants]				
Female	**203**	**25**	**53**	**281**
Male	**229**	**51**	**71**	**351**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Change in Serum Phosphorus for MCI-196 and Sevelamer [Time Frame: 52 weeks (Baseline-52 weeks)]

Measure Type	Primary
Measure Title	The Change in Serum Phosphorus for MCI-196 and Sevelamer
Measure Description	Change from Baseline to Week 52 (LOCF)
Time Frame	52 weeks (Baseline-52 weeks)
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 subjects who received enrolment number into MCI-196-E10, took at least 1 dose of study medication in original study and had at least 1 post-enrolment efficacy value after start of study medication in MCI-196-E10. Data collected from start of original studies to end of MCI-196-E10 were analysed for this population.

Reporting Groups

	Description
MCI-196 From E07 / E08 Studies	3, 6, 9, 12, or 15g / day as titrated
MCI-196 From E07 Study	3, 6, 9, 12, or 15g / day as titrated
Sevelamer From E07 Study	2.4, 4.8, 7.2, 9.6, or 12.0g / day as titrated

Measured Values

	MCI-196 From E07 / E08 Studies	**MCI-196 From E07 Study**	**Sevelamer From E07 Study**
Number of Participants Analyzed [units: participants]	**429**	**75**	**124**
The Change in Serum Phosphorus for MCI-196 and Sevelamer [units: mg / dL] Mean (Standard Deviation)	**-1.23 (1.78)**	**-1.47 (1.68)**	**-2.26 (1.82)**

No statistical analysis provided for The Change in Serum Phosphorus for MCI-196 and Sevelamer

2. Secondary: The Percent Change in Serum LDL-cholesterol for MCI-196 and Sevelamer [Time Frame: 52 weeks (Baseline-52 weeks)]

Measure Type	Secondary
Measure Title	The Percent Change in Serum LDL-cholesterol for MCI-196 and Sevelamer
Measure Description	Percent Change from Baseline to Week 52 (LOCF)
Time Frame	52 weeks (Baseline-52 weeks)
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 subjects who received enrolment number into MCI-196-E10, took at least 1 dose of study medication in original study and had at least 1 post-enrolment efficacy value after start of study medication in MCI-196-E10. Data collected from start of original studies to end of MCI-196-E10 were analysed for this population.

Reporting Groups

	Description
MCI-196 From E07 / E08 Studies	3, 6, 9, 12, or 15g / day as titrated
MCI-196 From E07 Study	3, 6, 9, 12, or 15g / day as titrated
Sevelamer From E07 Study	2.4, 4.8, 7.2, 9.6, or 12.0g / day as titrated

Measured Values

	MCI-196 From E07 / E08 Studies	MCI-196 From E07 Study	Sevelamer From E07 Study
Number of Participants Analyzed [units: participants]	**429**	**75**	**124**
The Percent Change in Serum LDL-cholesterol for MCI-196 and Sevelamer [units: percentage change of LDL-cholesterol] Mean (Standard Deviation)	**-26.22 (27.08)**	**-30.62 (20.12)**	**-28.66 (23.61)**

No statistical analysis provided for The Percent Change in Serum LDL-cholesterol for MCI-196 and Sevelamer

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
MCI-196 From E07/E08 Studies	3, 6, 9, 12, or 15g / day as titrated
MCI-196 From E07 Study	3, 6, 9, 12, or 15g / day as titrated
Sevelamer From E07 Study	2.4, 4.8, 7.2, 9.6, or 12.0g / day as titrated

Serious Adverse Events

	MCI-196 From E07/E08 Studies	MCI-196 From E07 Study	Sevelamer From E07 Study
Total, serious adverse events			
# participants affected / at risk	**74/432 (17.13%)**	**31/76 (40.79%)**	**48/124 (38.71%)**
Blood and lymphatic system disorders			
Anaemia			
# participants affected / at risk	**2/432 (0.46%)**	**2/76 (2.63%)**	**3/124 (2.42%)**
Cardiac disorders			
Acute coronary syndrome			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Acute myocardial infarction			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
Angina pectoris			

# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	2/124 (1.61%)
Angina unstable			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Atrial fibrillation			
# participants affected / at risk	5/432 (1.16%)	3/76 (3.95%)	0/124 (0.00%)
Atrioventricular block			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Atrioventricular block complete			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Bundle branch block left			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Cardiac arrest			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Cardiac failure			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Cardiac failure acute			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	1/124 (0.81%)
Cardiac failure congestive			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Cardio-respiratory arrest			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Cardiopulmonary failure			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Cardiovascular insufficiency			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Congestive cardiomyopathy			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Coronary artery disease			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Coronary artery insufficiency			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Coronary artery stenosis			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Ischaemic cardiomyopathy			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Myocardial infarction			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	1/124 (0.81%)
Myocardial ischaemia			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Pericarditis			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Ventricular fibrillation			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Ear and labyrinth disorders			
Vertigo			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	1/124 (0.81%)

Endocrine disorders			
Hyperparathyroidism			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Parathyroid gland enlargement			
# participants affected / at risk	**1/432 (0.23%)**	**1/76 (1.32%)**	**0/124 (0.00%)**
Eye disorders			
Iritis			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Gastrointestinal disorders			
Abdominal pain			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**2/124 (1.61%)**
Diarrhoea			
# participants affected / at risk	**0/432 (0.00%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
Diverticulum intestinal			
# participants affected / at risk	**1/432 (0.23%)**	**1/76 (1.32%)**	**0/124 (0.00%)**
Duodenitis			
# participants affected / at risk	**0/432 (0.00%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
Gastric ulcer			
# participants affected / at risk	**0/432 (0.00%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
Gastritis			
# participants affected / at risk	**0/432 (0.00%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
Gastritis erosive			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Gastrointestinal haemorrhage			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Haemorrhoids			
# participants affected / at risk	**1/432 (0.23%)**	**1/76 (1.32%)**	**0/124 (0.00%)**
Ileal perforation			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Peritonitis			
# participants affected / at risk	**3/432 (0.69%)**	**0/76 (0.00%)**	**2/124 (1.61%)**
Upper gastrointestinal haemorrhage			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
General disorders			
Cardiac death			
# participants affected / at risk	**1/432 (0.23%)**	**1/76 (1.32%)**	**0/124 (0.00%)**
Catheter related complication			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Catheter site haematoma			
# participants affected / at risk	**1/432 (0.23%)**	**1/76 (1.32%)**	**0/124 (0.00%)**
Catheter site haemorrhage			
# participants affected / at risk	**0/432 (0.00%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
Catheter site phlebitis			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**
Mass			
# participants affected / at risk	**1/432 (0.23%)**	**0/76 (0.00%)**	**0/124 (0.00%)**

Pyrexia			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Hepatobiliary disorders			
Bile duct stenosis			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Cholelithiasis			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Immune system disorders			
Anaphylactic reaction			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Infections and infestations			
Abdominal abscess			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Acute sinusitis			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Aeromona infection			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Arteriovenous fistula site infection			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Bronchitis			
# participants affected / at risk	2/432 (0.46%)	1/76 (1.32%)	0/124 (0.00%)
Bronchopneumonia			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Catheter sepsis			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Cellulitis			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Clostridium difficile colitis			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Furuncle			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Gangrene			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Pneumonia			
# participants affected / at risk	7/432 (1.62%)	3/76 (3.95%)	1/124 (0.81%)
Pyelonephritis chronic			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Pyonephrosis			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Salpingitis			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Sepsis			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Subcutaneous abscess			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Upper respiratory tract infection			

# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Urinary tract infection			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	1/124 (0.81%)
Wound sepsis			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Injury, poisoning and procedural complications			
Ankle fracture			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Arteriovenous fistula aneurysm			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Arteriovenous fistula site complication			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	1/124 (0.81%)
Arteriovenous fistula site haemorrhage			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Arteriovenous fistula thrombosis			
# participants affected / at risk	5/432 (1.16%)	1/76 (1.32%)	0/124 (0.00%)
Device failure			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Dialysis device complication			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Eye injury			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Femoral neck fracture			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Fibula fracture			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Periprosthetic fracture			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Procedural hypotension			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Radius fracture			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Road traffic accident			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Shunt malfunction			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Shunt occlusion			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	2/124 (1.61%)
Shunt thrombosis			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Vascular pseudoaneurysm			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Investigations			
Arteriogram coronary			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	2/124 (1.61%)
Hepatic enzyme increased			

# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Metabolism and nutrition disorders			
Dehydration			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Diabetes mellitus			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Fluid overload			
# participants affected / at risk	2/432 (0.46%)	1/76 (1.32%)	0/124 (0.00%)
Fluid retention			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Hyperglycaemia			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Hyperkalaemia			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Hypoglycaemia			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Metabolic disorder			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	1/124 (0.81%)
Rotator cuff syndrome			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Soft tissue haemorrhage			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung neoplasm malignant			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Squamous cell carcinoma			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Thyroid neoplasm			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Uterine cancer			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Nervous system disorders			
Brain stem ischaemia			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Carotid artery stenosis			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Cerebrovascular accident			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Encephalomalacia			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Epilepsy			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)

Haemorrhagic stroke			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Ischaemic stroke			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	2/124 (1.61%)
Loss of consciousness			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Subarachnoid haemorrhage			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Vertebrobasilar insufficiency			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Psychiatric disorders			
Confusional state			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Renal and urinary disorders			
Calculus bladder			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Reduced bladder capacity			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Renal artery thrombosis			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Renal failure chronic			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	2/124 (1.61%)
Genital haemorrhage			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
# participants affected / at risk	2/432 (0.46%)	1/76 (1.32%)	0/124 (0.00%)
Chronic obstructive pulmonary disease			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	1/124 (0.81%)
Dyspnoea			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	1/124 (0.81%)
Orthopnoea			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Pharyngeal haemorrhage			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Pleural effusion			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	1/124 (0.81%)
Pneumothorax			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Pulmonary oedema			
# participants affected / at risk	2/432 (0.46%)	0/76 (0.00%)	1/124 (0.81%)
Respiratory distress			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)

Respiratory failure			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Guttate psoriasis			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Skin ulcer			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Surgical and medical procedures			
Coronary arterial stent insertion			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Vascular disorders			
Accelerated hypertension			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Aortic stenosis			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Arterial occlusive disease			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Arteriosclerosis			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Arteriosclerosis obliterans			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Brachiocephalic vein stenosis			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	1/124 (0.81%)
Circulatory collapse			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	0/124 (0.00%)
Extremity necrosis			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	2/124 (1.61%)
Haematoma			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	2/124 (1.61%)
Hypertension			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	2/124 (1.61%)
Hypertensive crisis			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	3/124 (2.42%)
Hypovolaemic shock			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	0/124 (0.00%)
Peripheral vascular disorder			
# participants affected / at risk	0/432 (0.00%)	0/76 (0.00%)	1/124 (0.81%)
Venous insufficiency			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (0.00%)
Venous occlusion			
# participants affected / at risk	1/432 (0.23%)	0/76 (0.00%)	0/124 (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	2

Reporting Groups

	Description
MCI-196 From E07/E08 Studies	3, 6, 9, 12, or 15g / day as titrated
MCI-196 From E07 Study	3, 6, 9, 12, or 15g / day as titrated
Sevelamer From E07 Study	2.4, 4.8, 7.2, 9.6, or 12.0g / day as titrated

Other Adverse Events

	MCI-196 From E07/E08 Studies	MCI-196 From E07 Study	Sevelamer From E07 Study
Total, other (not including serious) adverse events			
# participants affected / at risk	**310/432 (71.76%)**	**75/76 (98.68%)**	**112/124 (90.32%)**
Blood and lymphatic system disorders			
Anaemia			
# participants affected / at risk	**34/432 (7.87%)**	**13/76 (17.11%)**	**22/124 (17.74%)**
Nephrogenic anaemia			
# participants affected / at risk	**6/432 (1.39%)**	**2/76 (2.63%)**	**1/124 (0.81%)**
Cardiac disorders			
Angina pectoris			
# participants affected / at risk	**5/432 (1.16%)**	**1/76 (1.32%)**	**4/124 (3.23%)**
Myocardial ischaemia			
# participants affected / at risk	**9/432 (2.08%)**	**0/76 (0.00%)**	**1/124 (0.81%)**
Ear and labyrinth disorders			
Vertigo			
# participants affected / at risk	**6/432 (1.39%)**	**1/76 (1.32%)**	**4/124 (3.23%)**
Endocrine disorders			
Hyperparathyroidism			
# participants affected / at risk	**14/432 (3.24%)**	**5/76 (6.58%)**	**12/124 (9.68%)**
Hyperparathyroidism secondary			
# participants affected / at risk	**5/432 (1.16%)**	**3/76 (3.95%)**	**4/124 (3.23%)**
Eye disorders			
Conjunctivitis			
# participants affected / at risk	**6/432 (1.39%)**	**2/76 (2.63%)**	**3/124 (2.42%)**
Gastrointestinal disorders			
Abdominal distension			
# participants affected / at risk	**14/432 (3.24%)**	**0/76 (0.00%)**	**1/124 (0.81%)**

Abdominal pain			
# participants affected / at risk	21/432 (4.86%)	9/76 (11.84%)	13/124 (10.48%)
Abdominal pain upper			
# participants affected / at risk	25/432 (5.79%)	8/76 (10.53%)	7/124 (5.65%)
Constipation			
# participants affected / at risk	32/432 (7.41%)	14/76 (18.42%)	14/124 (11.29%)
Diarrhoea			
# participants affected / at risk	31/432 (7.18%)	15/76 (19.74%)	20/124 (16.13%)
Duodenitis			
# participants affected / at risk	4/432 (0.93%)	2/76 (2.63%)	3/124 (2.42%)
Dyspepsia			
# participants affected / at risk	40/432 (9.26%)	13/76 (17.11%)	9/124 (7.26%)
Flatulence			
# participants affected / at risk	9/432 (2.08%)	2/76 (2.63%)	3/124 (2.42%)
Gastritis			
# participants affected / at risk	10/432 (2.31%)	3/76 (3.95%)	2/124 (1.61%)
Gastritis erosive			
# participants affected / at risk	9/432 (2.08%)	0/76 (0.00%)	0/124 (0.00%)
Gastrooesophageal reflux disease			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	1/124 (0.81%)
Nausea			
# participants affected / at risk	50/432 (11.57%)	8/76 (10.53%)	13/124 (10.48%)
Oesophagitis			
# participants affected / at risk	3/432 (0.69%)	3/76 (3.95%)	1/124 (0.81%)
Toothache			
# participants affected / at risk	3/432 (0.69%)	3/76 (3.95%)	3/124 (2.42%)
Vomiting			
# participants affected / at risk	37/432 (8.56%)	15/76 (19.74%)	13/124 (10.48%)
General disorders			
Asthenia			
# participants affected / at risk	19/432 (4.40%)	3/76 (3.95%)	2/124 (1.61%)
Non-cardiac chest pain			
# participants affected / at risk	4/432 (0.93%)	2/76 (2.63%)	2/124 (1.61%)
Oedema peripheral			
# participants affected / at risk	16/432 (3.70%)	9/76 (11.84%)	4/124 (3.23%)
Pyrexia			
# participants affected / at risk	12/432 (2.78%)	2/76 (2.63%)	7/124 (5.65%)
Infections and infestations			
Bronchitis			
# participants affected / at risk	15/432 (3.47%)	8/76 (10.53%)	11/124 (8.87%)
Catheter sepsis			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	1/124 (0.81%)
Cystitis			
# participants affected / at risk	3/432 (0.69%)	0/76 (0.00%)	5/124 (4.03%)
Gastroenteritis			
# participants affected / at risk	2/432 (0.46%)	0/76 (0.00%)	3/124 (2.42%)

Influenza			
# participants affected / at risk	13/432 (3.01%)	3/76 (3.95%)	8/124 (6.45%)
Nasopharyngitis			
# participants affected / at risk	13/432 (3.01%)	8/76 (10.53%)	14/124 (11.29%)
Pharyngitis			
# participants affected / at risk	7/432 (1.62%)	3/76 (3.95%)	5/124 (4.03%)
Respiratory tract infection			
# participants affected / at risk	10/432 (2.31%)	4/76 (5.26%)	0/124 (0.00%)
Respiratory tract infection viral			
# participants affected / at risk	9/432 (2.08%)	0/76 (0.00%)	0/124 (0.00%)
Rhinitis			
# participants affected / at risk	5/432 (1.16%)	2/76 (2.63%)	2/124 (1.61%)
Upper respiratory tract infection			
# participants affected / at risk	7/432 (1.62%)	4/76 (5.26%)	8/124 (6.45%)
Urinary tract infection			
# participants affected / at risk	5/432 (1.16%)	3/76 (3.95%)	6/124 (4.84%)
Injury, poisoning and procedural complications			
Arteriovenous fistula site complication			
# participants affected / at risk	7/432 (1.62%)	6/76 (7.89%)	2/124 (1.61%)
Arteriovenous fistula site haematoma			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	5/124 (4.03%)
Arteriovenous fistula thrombosis			
# participants affected / at risk	13/432 (3.01%)	3/76 (3.95%)	5/124 (4.03%)
Dialysis device complication			
# participants affected / at risk	3/432 (0.69%)	2/76 (2.63%)	1/124 (0.81%)
Haemodialysis-induced symptom			
# participants affected / at risk	22/432 (5.09%)	8/76 (10.53%)	13/124 (10.48%)
Limb injury			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	3/124 (2.42%)
Procedural hypertension			
# participants affected / at risk	14/432 (3.24%)	2/76 (2.63%)	6/124 (4.84%)
Procedural hypotension			
# participants affected / at risk	16/432 (3.70%)	6/76 (7.89%)	9/124 (7.26%)
Procedural pain			
# participants affected / at risk	3/432 (0.69%)	3/76 (3.95%)	1/124 (0.81%)
Investigations			
Blood parathyroid hormone increased			
# participants affected / at risk	14/432 (3.24%)	2/76 (2.63%)	7/124 (5.65%)
C-reactive protein increased			
# participants affected / at risk	5/432 (1.16%)	5/76 (6.58%)	7/124 (5.65%)
Electrocardiogram QT interval abnormal			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	0/124 (0.00%)
Haemoglobin decreased			
# participants affected / at risk	3/432 (0.69%)	0/76 (0.00%)	3/124 (2.42%)
Metabolism and nutrition disorders			
Decreased appetite			

# participants affected / at risk	13/432 (3.01%)	4/76 (5.26%)	3/124 (2.42%)
Fluid overload			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	3/124 (2.42%)
Fluid retention			
# participants affected / at risk	8/432 (1.85%)	2/76 (2.63%)	0/124 (0.00%)
Hyperkalaemia			
# participants affected / at risk	15/432 (3.47%)	6/76 (7.89%)	7/124 (5.65%)
Hyperphosphataemia			
# participants affected / at risk	7/432 (1.62%)	3/76 (3.95%)	2/124 (1.61%)
Hypervolaemia			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	0/124 (0.00%)
Hypocalcaemia			
# participants affected / at risk	32/432 (7.41%)	12/76 (15.79%)	10/124 (8.06%)
Hypoglycaemia			
# participants affected / at risk	4/432 (0.93%)	3/76 (3.95%)	1/124 (0.81%)
Iron deficiency			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	3/124 (2.42%)
Musculoskeletal and connective tissue disorders			
Arthralgia			
# participants affected / at risk	21/432 (4.86%)	3/76 (3.95%)	9/124 (7.26%)
Back pain			
# participants affected / at risk	14/432 (3.24%)	10/76 (13.16%)	6/124 (4.84%)
Bone pain			
# participants affected / at risk	6/432 (1.39%)	2/76 (2.63%)	5/124 (4.03%)
Muscle spasms			
# participants affected / at risk	9/432 (2.08%)	3/76 (3.95%)	1/124 (0.81%)
Musculoskeletal chest pain			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	3/124 (2.42%)
Musculoskeletal pain			
# participants affected / at risk	6/432 (1.39%)	4/76 (5.26%)	7/124 (5.65%)
Neck pain			
# participants affected / at risk	2/432 (0.46%)	0/76 (0.00%)	4/124 (3.23%)
Osteochondrosis			
# participants affected / at risk	13/432 (3.01%)	1/76 (1.32%)	0/124 (0.00%)
Pain in extremity			
# participants affected / at risk	9/432 (2.08%)	3/76 (3.95%)	13/124 (10.48%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Thyroid neoplasm			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	0/124 (0.00%)
Nervous system disorders			
Headache			
# participants affected / at risk	31/432 (7.18%)	9/76 (11.84%)	12/124 (9.68%)
Psychiatric disorders			
Anxiety			
# participants affected / at risk	5/432 (1.16%)	3/76 (3.95%)	2/124 (1.61%)

Insomnia			
# participants affected / at risk	6/432 (1.39%)	1/76 (1.32%)	4/124 (3.23%)
Renal and urinary disorders			
Anuria			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	0/124 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
# participants affected / at risk	3/432 (0.69%)	2/76 (2.63%)	0/124 (0.00%)
Chronic obstructive pulmonary disease			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	1/124 (0.81%)
Cough			
# participants affected / at risk	16/432 (3.70%)	8/76 (10.53%)	9/124 (7.26%)
Dyspnoea			
# participants affected / at risk	10/432 (2.31%)	6/76 (7.89%)	6/124 (4.84%)
Epistaxis			
# participants affected / at risk	6/432 (1.39%)	0/76 (0.00%)	3/124 (2.42%)
Oropharyngeal pain			
# participants affected / at risk	6/432 (1.39%)	3/76 (3.95%)	4/124 (3.23%)
Skin and subcutaneous tissue disorders			
Pruritus			
# participants affected / at risk	15/432 (3.47%)	3/76 (3.95%)	7/124 (5.65%)
Rash			
# participants affected / at risk	3/432 (0.69%)	2/76 (2.63%)	3/124 (2.42%)
Skin ulcer			
# participants affected / at risk	1/432 (0.23%)	1/76 (1.32%)	5/124 (4.03%)
Urticaria			
# participants affected / at risk	2/432 (0.46%)	1/76 (1.32%)	3/124 (2.42%)
Surgical and medical procedures			
Renal transplant			
# participants affected / at risk	12/432 (2.78%)	7/76 (9.21%)	5/124 (4.03%)
Vascular disorders			
Accelerated hypertension			
# participants affected / at risk	2/432 (0.46%)	2/76 (2.63%)	1/124 (0.81%)
Arteriosclerosis			
# participants affected / at risk	2/432 (0.46%)	1/76 (1.32%)	3/124 (2.42%)
Hypertension			
# participants affected / at risk	55/432 (12.73%)	23/76 (30.26%)	39/124 (31.45%)
Hypotension			
# participants affected / at risk	13/432 (3.01%)	5/76 (6.58%)	5/124 (4.03%)

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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Organization: Mitsubishi Tanabe Pharma Corporation
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Responsible Party:	Mitsubishi Tanabe Pharma Corporation
ClinicalTrials.gov Identifier:	NCT00542815 History of Changes
Other Study ID Numbers:	MCI-196-E10
Study First Received:	October 10, 2007
Results First Received:	September 16, 2014
Last Updated:	September 24, 2014
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency Italy: Ethics Committee Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products