Trial record **1 of 1** for: NCT00821821
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Safety and Pharmacokinetics of MCI-186 in Subjects With Acute Ischemic Stroke

This study has been completed.

Sponsor:
Mitsubishi Tanabe Pharma Corporation

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

ClinicalTrials.gov Identifier:
NCT00821821

First received: January 13, 2009
Last updated: April 7, 2014
Last verified: April 2014
History of Changes

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

Results First Received: January 5, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Acute Ischemic Stroke (AIS)
Interventions:	Drug: MCI-186 Drug: Placebo

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-186 Cohort1	Edaravone: circa 1000 mg / 72-hour infusion
MCI-186 Cohort2	Edaravone: circa 2000 mg / 72-hour infusion
Placebo Group	Cohort1:circa 1000mg / 72-hour infusion matching placebo Cohort2:circa 2000mg / 72-hour infusion matching placebo

Participant Flow: Overall Study

	MCI-186 Cohort1	MCI-186 Cohort2	Placebo Group
STARTED	12	13	11
COMPLETED	12	13	11
NOT COMPLETED	0	0	0

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-186 Cohort1	Edaravone: circa 1000 mg / 72-hour infusion
MCI-186 Cohort2	Edaravone: circa 2000 mg / 72-hour infusion
Placebo Group	Cohort1:circa 1000mg / 72-hour infusion matching placebo Cohort2:circa 2000mg / 72-hour infusion matching placebo
Total	Total of all reporting groups

Baseline Measures

	MCI-186 Cohort1	MCI-186 Cohort2	Placebo Group	Total
Number of Participants [units: participants]	12	13	11	36
Age [units: participants]				
<=18 years	0	0	0	0
Between 18 and 65 years	5	9	2	16
>=65 years	7	4	9	20
Gender [units: participants]				
Female	2	4	3	9
Male	10	9	8	27

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants That Experienced Adverse Events [Time Frame: 87days]

Measure Type	Primary
Measure Title	Number of Participants That Experienced Adverse Events
Measure Description	Additional Outcome Measures are included in Tables for Serious Adverse Events and Other Adverse Events to report their numbers and frequency.

Time Frame	87days
Safety Issue	Yes

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-186 Cohort1	Edaravone: circa 1000 mg / 72-hour infusion
MCI-186 Cohort2	Edaravone: circa 2000 mg / 72-hour infusion
Placebo Group	Cohort1:circa 1000mg / 72-hour infusion matching placebo Cohort2:circa 2000mg / 72-hour infusion matching placebo

Measured Values

	MCI-186 Cohort1	**MCI-186 Cohort2**	**Placebo Group**
Number of Participants Analyzed [units: participants]	**12**	**13**	**11**
Number of Participants That Experienced Adverse Events [units: participants]			
Deaths	**0**	**0**	**0**
Serious Adverse Events	**0**	**2**	**1**
Other Adverse Events	**12**	**10**	**10**

No statistical analysis provided for Number of Participants That Experienced Adverse Events

2. Secondary: Plasma MCI-186 Pharmacokinetics [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Plasma MCI-186 Pharmacokinetics
Measure Description	The geometric mean values of MCI-186 plasma concentration at the end of the infusion (at 72h) in cohorts 1 and 2 were determined.
Time Frame	72 hours
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.
The subjects with reliable measured values for plasma concentration were selected for pharmacokinetic analysis: 5 subjects in MCI-186 Cohort 1 and 11 subjects in MCI-186 Cohort 2.

Reporting Groups

	Description
MCI-186 Cohort1	Edaravone:circa 1000mg / 72-hour infusion

MCI-186 Cohort2	Edaravone:circa 2000mg / 72-hour infusion

Measured Values

	MCI-186 Cohort1	MCI-186 Cohort2
Number of Participants Analyzed [units: participants]	**5**	**11**
Plasma MCI-186 Pharmacokinetics [units: ng / ml] Geometric Mean (Geometric Coefficient of Variation)	**391 (45.81% to 3338%)**	**1595 (958.3% to 2655%)**

No statistical analysis provided for Plasma MCI-186 Pharmacokinetics

3. Secondary: mRS, NIHSS, Barthel Index [Time Frame: throughout study]

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	87 days
Additional Description	No text entered.

Reporting Groups

	Description
MCI-186 Cohort1	Edaravone: circa 1000mg / 72-hour infusion
MCI-186 Cohort2	Edaravone: circa 2000mg / 72-hour infusion
Placebo Group	Cohort1:circa 1000mg / 72-hour infusion matching placebo Cohort2:circa 2000mg / 72-hour infusion matching placebo

Serious Adverse Events

	MCI-186 Cohort1	MCI-186 Cohort2	Placebo Group
Total, serious adverse events			
# participants affected / at risk	**0/12 (0.00%)**	**2/13 (15.38%)**	**1/11 (9.09%)**
Metabolism and nutrition disorders			
Gout [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Nervous system disorders			
Hemiparesis [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Ischaemic Stroke [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**

1 Term from vocabulary, MedDRA 11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	87 days
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0

Reporting Groups

	Description
MCI-186 Cohort1	Edaravone: circa 1000mg / 72-hour infusion
MCI-186 Cohort2	Edaravone: circa 2000mg / 72-hour infusion
Placebo Group	Cohort1:circa 1000mg / 72-hour infusion matching placebo Cohort2:circa 2000mg / 72-hour infusion matching placebo

Other Adverse Events

	MCI-186 Cohort1	MCI-186 Cohort2	Placebo Group
Total, other (not including serious) adverse events			
# participants affected / at risk	**12/12 (100.00%)**	**10/13 (76.92%)**	**10/11 (90.91%)**
Cardiac disorders			
Atrial Fibrillation [1]			
# participants affected / at risk	**0/12 (0.00%)**	**2/13 (15.38%)**	**0/11 (0.00%)**
Bradycardia [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Eye disorders			
Cataract [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Vision Blurred [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Gastrointestinal disorders			
Abdominal Pain Lower [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Constipation [1]			
# participants affected / at risk	**1/12 (8.33%)**	**0/13 (0.00%)**	**2/11 (18.18%)**
Diarrhoea [1]			
# participants affected / at risk	**1/12 (8.33%)**	**0/13 (0.00%)**	**0/11 (0.00%)**
Dyspepsia [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Gastrooesophageal Reflux Disease [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Mouth Ulceration [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Nausea [1]			
# participants affected / at risk	**5/12 (41.67%)**	**1/13 (7.69%)**	**2/11 (18.18%)**

Vomiting [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	1/11 (9.09%)
General disorders			
Fatigue [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Infusion Site Phlebitis [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Oedema Peripheral [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Pyrexia [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Vessel Puncture Site Haematoma [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	1/11 (9.09%)
Infections and infestations			
Eczema Infected [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)
Groin Abscess [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Infusion Site Infection [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)
Pneumonia [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Sinusitis [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Urinary Tract Infection [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Investigations			
Blood Alkaline Phosphatase Increased [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)
Blood Creatine Phosphokinase Increased [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Blood Glucose Increased [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Blood Uric Acid Increased [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
C-Reactive Protein Increased [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Gamma-Glutamyltransferase Increased [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	1/11 (9.09%)
Hepatic Enzyme Increased [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Liver Function Test Abnormal [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)

Metabolism and nutrition disorders			
Diabetes Mellitus [1]			
# participants affected / at risk	**1/12 (8.33%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Hypercholesterolaemia [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**2/11 (18.18%)**
Hyperglycaemia [1]			
# participants affected / at risk	**0/12 (0.00%)**	**2/13 (15.38%)**	**0/11 (0.00%)**
Hyperlipidaemia [1]			
# participants affected / at risk	**2/12 (16.67%)**	**0/13 (0.00%)**	**0/11 (0.00%)**
Hyponatraemia [1]			
# participants affected / at risk	**1/12 (8.33%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Musculoskeletal and connective tissue disorders			
Back Pain [1]			
# participants affected / at risk	**1/12 (8.33%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Muscle Spasms [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Myalgia [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Osteoarthritis [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Nervous system disorders			
Cerebrovascular Accident [1]			
# participants affected / at risk	**1/12 (8.33%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Dizziness [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Headache [1]			
# participants affected / at risk	**4/12 (33.33%)**	**4/13 (30.77%)**	**4/11 (36.36%)**
Hypoaesthesia [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Neuralgia [1]			
# participants affected / at risk	**1/12 (8.33%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Paraesthesia [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Simple Partial Seizures [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Somnolence [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Speech Disorder [1]			
# participants affected / at risk	**0/12 (0.00%)**	**1/13 (7.69%)**	**0/11 (0.00%)**
Transient Ischaemic Attack [1]			
# participants affected / at risk	**0/12 (0.00%)**	**0/13 (0.00%)**	**1/11 (9.09%)**
Psychiatric disorders			
Anxiety [1]			

# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Depression [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Insomnia [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	0/11 (0.00%)
Renal and urinary disorders			
Urethral Haemorrhage [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Urinary Incontinence [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Respiratory, thoracic and mediastinal disorders			
Epistaxis [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)
Pleural Fibrosis [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)
Pulmonary Oedema [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)
Skin and subcutaneous tissue disorders			
Erythema [1]			
# participants affected / at risk	0/12 (0.00%)	0/13 (0.00%)	1/11 (9.09%)
Rash [1]			
# participants affected / at risk	1/12 (8.33%)	0/13 (0.00%)	1/11 (9.09%)
Stasis Dermatitis [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)
Vascular disorders			
Hypertension [1]			
# participants affected / at risk	3/12 (25.00%)	2/13 (15.38%)	4/11 (36.36%)
Hypotension [1]			
# participants affected / at risk	0/12 (0.00%)	1/13 (7.69%)	0/11 (0.00%)

1 Term from vocabulary, MedDRA 11.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: No text entered.

Results Point of Contact:

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

Publications of Results:

Kaste M, Murayama S, Ford GA, Dippel DW, Walters MR, Tatlisumak T; MCI-186 study group. Safety, tolerability and pharmacokinetics of MCI-186 in patients with acute ischemic stroke: new formulation and dosing regimen. Cerebrovasc Dis. 2013;36(3):196-204. doi: 10.1159/000353680. Epub 2013 Oct 12. Erratum in: Cerebrovasc Dis. 2013;36(5-6):461.

Responsible Party:	Mitsubishi Tanabe Pharma Corporation
ClinicalTrials.gov Identifier:	NCT00821821 History of Changes
Other Study ID Numbers:	MCI-186-E04
Study First Received:	January 13, 2009
Results First Received:	January 5, 2014
Last Updated:	April 7, 2014
Health Authority:	Finland: Finnish Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) United Kingdom: Medicines and Healthcare Products Regulatory Agency