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ID: TAK-242_301 Efficacy and Safety of Resatorvid in Patients With Sepsis-induced Cardiovascular and Respiratory Failure NCT00633477

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Participant Flow

Recruitment Details	Participants took part in the sudy at 11 centers in Japan and 1 center in the United States from 26 February 2008 to 20 February 2009 (day the decision was taken to terminate the study) .
Pre-Assignment Details	Participants who met 3 of the 4 systemic inflammatory response syndrome (SIRS) criteria and receiving parentaeral antimicrobial therapy for bacterial or fungal infection prior to enrollment and met the key organ failure criteria within 36 hours of planned study drug administration were randomized to receive resatorvid or placebo.

Arm/Group Title	**Resatorvid**	**Placebo**	Total (Not public)
Arm/Group Description	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours.	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.	
Period Title: Overall Study			
Started	7 [1]	11	18
Randomized But Not Treated	1	0	1
Prematurely Discontinued Study Drug	1	0	1
Completed Study Through Day 28	4	8	12
Completed	5 [2]	11 [3]	16
Not Completed	2	0	2
Reason Not Completed			
Death	1	0	1
Randomized but not treated	1	0	1
(Not Public)	Not Completed = 2 Total from all reasons = 2	Not Completed = 0 Total from all reasons = 0	

[1] Seven subjects were randomized, however, one was not treated.

[2] Include all subjects who could be evaluated for 28-d survival.

[3] Include all subjects who could be evaluated for 28-d survival.

Baseline Characteristics

Arm/Group Title	**Resatorvid 2.4 mg/kg/Day**	**Placebo**	**Total**
Arm/Group Description	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.	
Overall Number of Baseline Participants	6	11	**17**
Baseline Analysis Population Description	[Not specified]		
Age, Continuous			
Mean (Standard Deviation)			
Units: years	76.7 (5.28)	77.8 (13.56)	77.4 (11.14)
Age, Customized			
Measure Type: Number			
Units: Participants			
18 - <45	0	0	0
45 - <60	0	1	1
60 - <75	2	3	5
≥75	4	7	11
Gender, Male/Female			
Measure Type: Number			
Units: participants			
Female	0	4	4
Male	6	7	13
Race			
Measure Type: Number			
Units: Participants			
American Indian or Alaska Native	0	0	0
Asian	6	10	16
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	1	1
More than one race	0	0	0
Ethnicity			
Measure Type: Number			
Units: Participants			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	1	1
Unknown or Not Reported	6	10	16
Weight			
Mean (Standard Deviation)			
Units: kg	54.27 (12.9)	58.24 (17.1)	56.84 (15.4)
Height			
Mean (Standard Deviation)			
Units: cm	158.3 (6.0)	160.7 (7.4)	159.9 (6.9)
Body Mass Index			

Mean (Standard Deviation) **Units: kg/m2**	21.46 (3.97)	22.59 (6.12)	22.19 (5.36)
Smoking Classification **Measure Type: Number** **Units: Participant**			
Never smoked	2	4	6
Current smoker	0	3	3
Ex-smoker	3	4	7
Smoking history not available	1	0	1

Outcome Measures

1. Primary Outcome

Title: All-cause Mortality
NOTE : The Title and Time Frame pair are not unique.

Description: Mortality regardless of cause at Day 28

Time Frame: Day 28

Safety Issue? Yes

Outcome Measure Data

Analysis Population Description
Participants who received study drug.

Arm/Group Title	**Resatorvid**	**Placebo**
Arm/Group Description:	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours.	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.
Number of Participants Analyzed	6	11
Measure Type: Number Units: Participants		
Number participants Analyzed	6	11
Number Alive	4	8
Number not alive	2	3

2. Primary Outcome

Title: All-cause Mortality
NOTE : The Title and Time Frame pair are not unique.

Description: Mortality regardless of cause at Day 28

Time Frame: Day 28

Safety Issue? Yes

Outcome Measure Data

Analysis Population Description
Participants who received study drug

Arm/Group Title	Resatorvid	Placebo
Arm/Group Description:	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours.	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.
Number of Participants Analyzed	6	11
Measure Type: Number Units: Percent of Participant		
Percent Alive	66.7	72.7
Percent Not alive	33.7	27.3

3. Secondary Outcome

Title: ICU Free Days
Description: Number days participant was not in ICU
Time Frame: Day 28
Safety Issue? No

Outcome Measure Data

Analysis Population Description
This study was terminated early when 17 subjects had received treatment.

Arm/Group Title	Resatorvid	Placebo
Arm/Group Description:	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours.	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.
Number of Participants Analyzed	6	11
Measure Type: Number Units: days	NA [1]	NA [1]

Why Data Not Available:
[1] This study was terminated early when only 17 subjects had received treatment.

4. Secondary Outcome

Title: Vasopressor Free Days.

Description: Number days participant did not need vasopressors.

Time Frame: Day 28

Safety Issue? No

Outcome Measure Data

Analysis Population Description

This study was terminated early when 17 subjects had received treatment.

Arm/Group Title	**Resatorvid**	**Placebo**
Arm/Group Description:	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours.	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.
Number of Participants Analyzed	6	11
Measure Type: Number Units: days	NA [1]	NA [1]

Why Data Not Available:

[1] This study was terminated early when 17 subjects had received treatment.

5. Secondary Outcome

Title: Ventilator Free Days.

Description: Number days participant was not on Ventilattor support.

Time Frame: Day 28

Safety Issue? No

Outcome Measure Data

Analysis Population Description

This study was terminated early when 17 subjects had received treatment.

Arm/Group Title	**Resatorvid**	**Placebo**
Arm/Group Description:	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours.	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.
Number of Participants Analyzed	6	11
Measure Type: Number Units: Days	NA [1]	NA [1]

Why Data Not Available:

[1] This study was terminated early when 17 subjects had received treatment.

Adverse Events

Time Frame	Treatment-emergent adverse events are adverse events that started after the first dose of double-blind study drug and no more than 14 days (or 30 days for a serious adverse event) after the last dose of double-blind study drug
Additional Description	At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.
Source Vocabulary Name	MedDRA (11.0)
Assessment Type	Systematic Assessment

Arm/Group Title	Resatorvid	Placebo
Arm/Group Description	Resatorvid 1.2 mg/kg given as a 30-minute loading dose followed by 2.4 mg/kg/day given as a continuous infusion for 96 hours.	Placebo given as a 30-minute loading dose followed by a continuous infusion for 96 hours.

Serious Adverse Events

	Resatorvid	**Placebo**

	Affected / at Risk (%)	Affected / at Risk (%)
Total	1/6 (16.67%)	3/11 (27.27%)
General disorders		
Inflamation † A	0/6 (0%)	1/11 (9.09%)
Infections and infestations		
Sepsis [1] † A	0/6 (0%)	2/11 (18.18%)
Septic shcok † A	1/6 (16.67%)	0/11 (0%)
Nervous system disorders		
Anoxic encephalopathy † A	0/6 (0%)	1/11 (9.09%)
Intraventricular haemorrhage † A	0/6 (0%)	1/11 (9.09%)
Renal and urinary disorders		
Renal failure Acute † A	0/6 (0%)	1/11 (9.09%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.0)

[1] Death??

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Resatorvid	**Placebo**
	Affected / at Risk (%)	Affected / at Risk (%)
Total	4/6 (66.67%)	6/11 (54.55%)
Blood and lymphatic system disorders		
Anemia † A	0/6 (0%)	1/11 (9.09%)
Disseminated Intravascular coagulation † A	0/6 (0%)	1/11 (9.09%)
Thrombocytopenia † A	0/6 (0%)	1/11 (9.09%)
Cardiac disorders		
Atrial Fibrilation † A	0/6 (0%)	2/11 (18.18%)
Atrial Flutter † A	0/6 (0%)	1/11 (9.09%)
Ventricular Tachycardia † A	0/6 (0%)	1/1 (100%)
Gastrointestinal disorders		
Diarrhoea † A	3/6 (50%)	0/11 (0%)
General disorders		
Hypothermia † A	1/6 (16.67%)	0/11 (0%)
Oedema Peripheral † A	0/6 (0%)	1/11 (9.09%)
Hepatobiliary disorders		
Hepatic function abnormal † A	1/6 (16.67%)	1/11 (9.09%)
Infections and infestations		
Septic shock † A	0/6 (0%)	1/11 (9.09%)
Investigations		
Blood Amylase Increased † A	0/6 (0%)	1/11 (9.09%)
Blood Bilirubin Increased † A	1/6 (16.67%)	0/11 (0%)
Blood Cholesterol Increased † A	0/6 (0%)	1/11 (9.09%)
Blood Methaemoglobin present † A	1/6 (16.67%)	0/11 (0%)
Platelet count decreased † A	1/6 (16.67%)	0/11 (0%)

†

White Blood cell count increased [A]	1/6 (16.67%)	0/11 (0%)
Metabolism and nutrition disorders		
Hypophosphataemia † [A]	0/6 (0%)	1/11 (9.09%)
Metabolic Acidosis † [A]	0/6 (0%)	1/11 (9.09%)
Psychiatric disorders		
Delirium † [A]	1/6 (16.67%)	0/11 (0%)
Respiratory, thoracic and mediastinal disorders		
Respirotory Acidosis † [A]	1/6 (16.67%)	0/11 (0%)
Skin and subcutaneous tissue disorders		
Rash † [A]	0/6 (0%)	1/11 (9.09%)
Vascular disorders		
Hypotension † [A]	0/6 (0%)	1/11 (9.09%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.0)

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

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

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

No publication related to study results will be published prior to publication of a multi-center report submitted for publication within 18 months after conclusion or termination of a study at all study sites. Results publications will be submitted to sponsor for review 60 days in advance of publication. Sponsor can require removal of confidential information unrelated to study results. Sponsor can embargo a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact

Name/Official Title: Takeda Study Registration Call Center
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