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Trial record **1 of 1** for: CCBC134A2402

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Efficacy and Safety of Daptomycin Versus Vancomycin or Teicoplanin for Treatment of Complicated Skin and Soft Tissue Infections

This study has been terminated.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00430937

First received: February 1, 2007
Last updated: July 10, 2012
Last verified: July 2012
History of Changes

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Results First Received: December 7, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Skin Diseases, Infectious Soft Tissue Infections
Interventions:	Drug: Daptomycin Drug: Vancomycin Drug: Teicoplanin

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
194 participants were randomized; 5 participants were not exposed to study drug by mistake; therefore, only 189 participants received study drug.

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
Daptomycin	Daptomycin 4 mg/kg intravenous (i.v.) once daily
Pooled Comparator	Vancomycin 1 g intravenous (i.v.) twice daily or Teicoplanin 400 mg i.v. once daily following a loading dose of 400 mg administered at 0, 12 and 24 hours on day one.

Participant Flow: Overall Study

	Daptomycin	Pooled Comparator
STARTED	97 [1]	92
COMPLETED	70	64
NOT COMPLETED	27	28
Adverse Event	3	8
Death	0	1
Lost to Follow-up	6	6
Withdrawal by Subject	5	2
Protocol Violation	3	2
Lack of Efficacy	6	5
Inappropriate enrollment	2	1
Administrative reasons	1	0
Protocol discontinuation criteria met	1	2
Unable to classify	0	1

[1] Additional 5 participants were randomized; however, they were not exposed to study drug by mistake.

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
Daptomycin	Daptomycin 4 mg/kg intravenous (i.v.) once daily
Pooled Comparator	Vancomycin 1 g intravenous (i.v.) twice daily or Teicoplanin 400 mg i.v. once daily following a loading dose of 400 mg administered at 0, 12 and 24 hours on day one.
Total	Total of all reporting groups

Baseline Measures

	Daptomycin	Pooled Comparator	Total
Number of Participants [units: participants]	97	92	189
Age, Customized [units: Participants]			
< 65 years	62	61	123
>=65 years	35	31	66
Gender [units: participants]			
Female	36	41	77
Male	61	51	112

Outcome Measures

Hide All Outcome Measures

1. Primary: Clinical Success as Measured by Comparing the Participants Signs and Symptoms at the "Test of Cure" (TOC) Visit to Those Recorded at Study Baseline in the Clinically Evaluable Population. [Time Frame: Baseline to TOC Visit (7-14 days after end of treatment) up to 4 weeks]

Measure Type	Primary
Measure Title	Clinical Success as Measured by Comparing the Participants Signs and Symptoms at the "Test of Cure" (TOC) Visit to Those Recorded at Study Baseline in the Clinically Evaluable Population.
Measure Description	Success: Total resolution of clinically significant signs and symptoms of the infection site (cure) or improvement to such a level that no further antibacterial therapy was required (improvement). Failure: Persistence or progression of signs and symptoms after at least 3 days of study therapy, or development of new signs and symptoms at the infection site, or concomitant or additional antibacterial therapy with documented activity against isolated organisms, or a treatment duration greater than 14 days, or requirement of a major surgical procedure as adjunct or follow-up therapy.
Time Frame	Baseline to TOC Visit (7-14 days after end of treatment) up to 4 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.
The clinically evaluable population was used for the efficacy analysis. It included all patients who met the criteria for cSSTI as listed in the Protocol, had no substantive protocol deviation, had a sponsor clinical response assessment of “success” or “failure” at the assessment visit, and had a specified baseline primary site of infection.

Reporting Groups

	Description
Daptomycin	Daptomycin 4 mg/kg intravenous (i.v.) once daily
Pooled Comparator	Vancomycin 1 g intravenous (i.v.) twice daily or Teicoplanin 400 mg i.v. once daily following a loading dose of 400 mg administered at 0, 12 and 24 hours on day one.

Measured Values

	Daptomycin	**Pooled Comparator**
Number of Participants Analyzed [units: participants]	**58**	**47**
Clinical Success as Measured by Comparing the Participants Signs and Symptoms at the "Test of Cure" (TOC) Visit to Those Recorded at Study Baseline in the Clinically Evaluable Population. [units: Participants]		
Clinical Success	**53**	**41**
Clinical Failure	**5**	**6**

No statistical analysis provided for Clinical Success as Measured by Comparing the Participants Signs and Symptoms at the "Test of Cure" (TOC) Visit to Those Recorded at Study Baseline in the Clinically Evaluable Population.

2. Secondary: Microbiological Efficacy Measured by the Number of Participants Achieving Bacteriological Eradication of Gram-positive Baseline Pathogens at the TOC Visit. [Time Frame: Baseline to TOC Visit (7-14 days after end of treatment) up to 4 weeks]

Measure Type	Secondary
Measure Title	Microbiological Efficacy Measured by the Number of Participants Achieving Bacteriological Eradication of Gram-positive Baseline Pathogens at the TOC Visit.
Measure Description	Microbiological Success: All infecting Gram-positive pathogens isolated at baseline were eradicated at the TOC evaluation and a superinfecting pathogen was not isolated either prior to or at the TOC evaluation. Microbiological Failure: Persistence of one or more infecting Gram-positive pathogens or isolation of a superinfecting pathogen prior to or at the TOC evaluation.
Time Frame	Baseline to TOC Visit (7-14 days after end of treatment) up to 4 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.
Population analyzed consisted of patients from the clinically evaluable population who had microbiological assessments.

Reporting Groups

	Description
Daptomycin	Daptomycin 4 mg/kg intravenous (i.v.) once daily
Pooled Comparator	Vancomycin 1 g intravenous (i.v.) twice daily or Teicoplanin 400 mg i.v. once daily following a loading dose of 400 mg administered at 0, 12 and 24 hours on day one.

Measured Values

	Daptomycin	**Pooled Comparator**
Number of Participants Analyzed [units: participants]	**57**	**43**
Microbiological Efficacy Measured by the Number of Participants Achieving Bacteriological Eradication of Gram-positive Baseline Pathogens at the TOC Visit. [units: Participants]		
Microbiological Success	**56**	**39**
Microbiological Failure	**1**	**4**

No statistical analysis provided for Microbiological Efficacy Measured by the Number of Participants Achieving Bacteriological Eradication of Gram-positive Baseline Pathogens at the TOC Visit.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Daptomycin	Daptomycin 4 mg/kg intravenous (i.v.) once daily
Pooled Comparator	Vancomycin 1 g intravenous (i.v.) twice daily or Teicoplanin 400 mg i.v. once daily following a loading dose of 400 mg administered at 0, 12 and 24 hours on day one.

Serious Adverse Events

	Daptomycin	Pooled Comparator
Total, serious adverse events		
# participants affected / at risk	**17/97 (17.53%)**	**16/92 (17.39%)**
Blood and lymphatic system disorders		
Thrombocytopenia † 1		
# participants affected / at risk	**0/97 (0.00%)**	**1/92 (1.09%)**
Cardiac disorders		
Cardiac Arrest † 1		
# participants affected / at risk	**0/97 (0.00%)**	**1/92 (1.09%)**
Gastrointestinal disorders		
Crohn's Disease † 1		
# participants affected / at risk	**0/97 (0.00%)**	**1/92 (1.09%)**
Inguinal Hernia † 1		
# participants affected / at risk	**1/97 (1.03%)**	**0/92 (0.00%)**
General disorders		
Impaired Healing † 1		
# participants affected / at risk	**0/97 (0.00%)**	**1/92 (1.09%)**
Induration † 1		
# participants affected / at risk	**1/97 (1.03%)**	**0/92 (0.00%)**
Infections and infestations		
Abscess Limb † 1		
# participants affected / at risk	**0/97 (0.00%)**	**1/92 (1.09%)**
Cellulitis † 1		
# participants affected / at risk	**1/97 (1.03%)**	**0/92 (0.00%)**
Erysipelas † 1		
# participants affected / at risk	**2/97 (2.06%)**	**0/92 (0.00%)**
Haemophilus Bacteraemia † 1		
# participants affected / at risk	**1/97 (1.03%)**	**0/92 (0.00%)**
Necrotising Fasciitis † 1		
# participants affected / at risk	**0/97 (0.00%)**	**1/92 (1.09%)**
Pneumonia † 1		
# participants affected / at risk	**2/97 (2.06%)**	**1/92 (1.09%)**
Staphylococcal Skin Infection † 1		
# participants affected / at risk	**1/97 (1.03%)**	**0/92 (0.00%)**
Injury, poisoning and procedural complications		
Open Wound † 1		
# participants affected / at risk	**0/97 (0.00%)**	**1/92 (1.09%)**
Investigations		
Creatinine Renal Clearance Decreased † 1		
# participants affected / at risk	**1/97 (1.03%)**	**0/92 (0.00%)**
Metabolism and nutrition disorders		
Diabetic Foot † 1		

# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)
Musculoskeletal and connective tissue disorders		
Arthritis † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Acute Myeloid Leukaemia † 1		
# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)
Nervous system disorders		
Haemorrhage Intracranial † 1		
# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)
Renal and urinary disorders		
Renal Failure † 1		
# participants affected / at risk	1/97 (1.03%)	1/92 (1.09%)
Renal Failure Acute † 1		
# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)
Reproductive system and breast disorders		
Acquired Hydrocele † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Haemothorax † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Pleural Effusion † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Pulmonary Oedema † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Skin and subcutaneous tissue disorders		
Dermatitis † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Drug Eruption † 1		
# participants affected / at risk	0/97 (0.00%)	2/92 (2.17%)
Eczema Nummular † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Pruritus † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Psoriasis † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Skin Ulcer † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Surgical and medical procedures		
Skin Graft † 1		
# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)
Vascular disorders		
Arterial Occlusive Disease † 1		

# participants affected / at risk	2/97 (2.06%)	0/92 (0.00%)
Femoral Artery Occlusion † 1		
# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)
Hypertension † 1		
# participants affected / at risk	1/97 (1.03%)	0/92 (0.00%)
Peripheral Ischaemia † 1		
# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)
Vasculitis † 1		
# participants affected / at risk	0/97 (0.00%)	1/92 (1.09%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

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	5%

Reporting Groups

	Description
Daptomycin	Daptomycin 4 mg/kg intravenous (i.v.) once daily
Pooled Comparator	Vancomycin 1 g intravenous (i.v.) twice daily or Teicoplanin 400 mg i.v. once daily following a loading dose of 400 mg administered at 0, 12 and 24 hours on day one.

Other Adverse Events

	Daptomycin	Pooled Comparator
Total, other (not including serious) adverse events		
# participants affected / at risk	26/97 (26.80%)	25/92 (27.17%)
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	8/97 (8.25%)	1/92 (1.09%)
Diarrhoea † 1		
# participants affected / at risk	6/97 (6.19%)	4/92 (4.35%)
Nausea † 1		
# participants affected / at risk	5/97 (5.15%)	5/92 (5.43%)
Investigations		
Alanine Aminotransferase Increased † 1		
# participants affected / at risk	2/97 (2.06%)	7/92 (7.61%)
Aspartate Aminotransferase Increased † 1		
# participants affected / at risk	1/97 (1.03%)	5/92 (5.43%)
Blood Creatine Phosphokinase Increased † 1		
# participants affected / at risk	1/97 (1.03%)	5/92 (5.43%)

Blood Lactate Dehydrogenase Increased † 1		
# participants affected / at risk	**1/97 (1.03%)**	**5/92 (5.43%)**
Blood Pressure Increased † 1		
# participants affected / at risk	**0/97 (0.00%)**	**6/92 (6.52%)**
Blood Urea Increased † 1		
# participants affected / at risk	**1/97 (1.03%)**	**7/92 (7.61%)**
Metabolism and nutrition disorders		
Hypokalaemia † 1		
# participants affected / at risk	**6/97 (6.19%)**	**5/92 (5.43%)**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**5/97 (5.15%)**	**4/92 (4.35%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

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:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00430937 History of Changes
Other Study ID Numbers:	**CCBC134A2402**
Study First Received:	February 1, 2007
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