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Trial record **1 of 1** for: CERL080AIT09

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Efficacy and Tolerability of Full Dose Enteric-coated Mycophenolate Sodium, in Addition to Cyclosporine for Microemulsion Reduced Dose, in Maintenance Renal Transplant Recipients

This study has been terminated.

(The study has been stopped because of the lack of enrollment)

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00434590

First received: February 12, 2007
Last updated: March 8, 2011
Last verified: March 2011
History of Changes

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Results First Received: December 13, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Prevention
Condition:	Kidney Transplantation
Intervention:	Drug: Enteric coated mycophenolate sodium (Myfortic®)

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
Full Dose Myfortic® and Reduced Dose Neoral®	The administration of gradual dose increased to reach 1440 mg/day (V4) of enteric-coated mycophenolate sodium (Myfortic®, EC-MPS) with simultaneous dose reduction of micro emulsion cyclosporine (Neoral®, CsA-ME) given to maintenance kidney transplant patients previously treated with reduced-dose mycophenolate mofetil (MMF) and standard dose CsA-ME
Standard Dose of Myfortic® and Standard Dose of CsA-ME	Patients received unchanged dose of Myfortic® (equimolar to the prior established dose MMF) and unchanged standard dose of CsA-ME.

Participant Flow: Overall Study

	Full Dose Myfortic® and Reduced Dose Neoral®	Standard Dose of Myfortic® and Standard Dose of CsA-ME
STARTED	5	5
COMPLETED	0 [1]	0
NOT COMPLETED	5	5
Administrative problems	5	5

[1] All patients randomized had study discontinued because of premature study termination.

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
Full Dose Myfortic® and Reduced Dose Neoral®	The administration of gradual dose increased to reach 1440 mg/day (V4) of enteric-coated mycophenolate sodium (Myfortic®, EC-MPS) with simultaneous dose reduction of micro emulsion cyclosporine (Neoral®, CsA-ME) given to maintenance kidney transplant patients previously treated with reduced-dose mycophenolate mofetil (MMF) and standard dose CsA-ME
Standard Dose of Myfortic® and Standard Dose of CsA-ME	Patients received unchanged dose of Myfortic® (equimolar to the prior established dose MMF) and unchanged standard dose of CsA-ME.
Total	Total of all reporting groups

Baseline Measures

	Full Dose Myfortic® and Reduced Dose Neoral®	Standard Dose of Myfortic® and Standard Dose of CsA-ME	Total
Number of Participants [units: participants]	**5**	**5**	**10**
Age [units: Years] Mean (Standard Deviation)	**52.4 (13.8)**	**58.0 (12.5)**	**55.2 (12.8)**
Gender [units: participants]			
Female	**4**	**3**	**7**
Male	**1**	**2**	**3**

Outcome Measures

1. Primary: Renal Function, as Assessed by Glomerular Filtration Rate (GFR) at 12 Months [Time Frame: 12 months]

Hide Outcome Measure 1

Measure Type	Primary

Measure Title	Renal Function, as Assessed by Glomerular Filtration Rate (GFR) at 12 Months
Measure Description	The 12 month change from baseline (visit 2) in the glomerular filtration rate using the abbreviated Modification of Diet in Renal Disease (MDRD) formula to calculate GFR using the participant's serum creatinine, age, gender and ethnicity.
Time Frame	12 months
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.
Study was terminated without analysis (small sample size).

Reporting Groups

	Description
Full Dose Myfortic® and Reduced Dose Neoral®	The administration of gradual dose increased to reach 1440 mg/day (V4) of enteric-coated mycophenolate sodium (Myfortic®, EC-MPS) with simultaneous dose reduction of micro emulsion cyclosporine (Neoral®, CsA-ME) given to maintenance kidney transplant patients previously treated with reduced-dose mycophenolate mofetil (MMF) and standard dose CsA-ME
Standard Dose of Myfortic® and Standard Dose of CsA-ME	Patients received unchanged dose of Myfortic® (equimolar to the prior established dose MMF) and unchanged standard dose of CsA-ME.

Measured Values

	Full Dose Myfortic® and Reduced Dose Neoral®	**Standard Dose of Myfortic® and Standard Dose of CsA-ME**
Number of Participants Analyzed [units: participants]	**0**	**0**
Renal Function, as Assessed by Glomerular Filtration Rate (GFR) at 12 Months [units: mL/min] Mean (Standard Deviation)		

No statistical analysis provided for Renal Function, as Assessed by Glomerular Filtration Rate (GFR) at 12 Months

2. Secondary: Creatinine Clearance at 12 Months [Time Frame: 12 months]
Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

3. Secondary: Serum Creatinine at 12 Months [Time Frame: 12 months]
Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

4. Secondary: Reciprocal Slope of Serum Creatinine (mg/dL) or Micromole/l at 12 Months [Time Frame: 12 months]
Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

5. Secondary: Biopsy Proven Acute Rejections and Clinically Confirmed Acute Rejection at 12 Months [Time Frame: 12 months]
Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

6. Secondary: Chronic Rejection as Confirmed by Renal Biopsy at 12 Months [Time Frame: 12 months]
Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Reporting Groups

	Description
Full Dose Myfortic® and Reduced Dose Neoral®	The administration of gradual dose increased to reach 1440 mg/day (V4) of enteric-coated mycophenolate sodium (Myfortic®, EC-MPS) with simultaneous dose reduction of micro emulsion cyclosporine (Neoral®, CsA-ME) given to maintenance kidney transplant patients previously treated with reduced-dose mycophenolate mofetil (MMF) and standard dose CsA-ME
Standard Dose of Myfortic® and Standard Dose of CsA-ME	Patients received unchanged dose of Myfortic® (equimolar to the prior established dose MMF) and unchanged standard dose of CsA-ME.

Serious Adverse Events

	Full Dose Myfortic® and Reduced Dose Neoral®	Standard Dose of Myfortic® and Standard Dose of CsA-ME
Total, serious adverse events		
# participants affected / at risk	**0/5 (0.00%)**	**0/5 (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	5%

Reporting Groups

	Description
Full Dose Myfortic® and Reduced Dose Neoral®	The administration of gradual dose increased to reach 1440 mg/day (V4) of enteric-coated mycophenolate sodium (Myfortic®, EC-MPS) with simultaneous dose reduction of micro emulsion cyclosporine (Neoral®, CsA-ME) given to maintenance kidney transplant patients previously treated with reduced-dose mycophenolate mofetil (MMF) and standard dose CsA-ME
Standard Dose of Myfortic® and Standard Dose of CsA-ME	Patients received unchanged dose of Myfortic® (equimolar to the prior established dose MMF) and unchanged standard dose of CsA-ME.

Other Adverse Events

	Full Dose Myfortic® and Reduced Dose Neoral®	Standard Dose of Myfortic® and Standard Dose of CsA-ME
Total, other (not including serious) adverse events		
# participants affected / at risk	**2/5 (40.00%)**	**4/5 (80.00%)**
Blood and lymphatic system disorders		
Leukopenia † 1		
# participants affected / at risk	**1/5 (20.00%)**	**0/5 (0.00%)**
Eye disorders		
Conjunctival irritation † 1		

# participants affected / at risk	**0/5 (0.00%)**	**1/5 (20.00%)**
Gastrointestinal disorders		
Haemorrhoids † 1		
# participants affected / at risk	**0/5 (0.00%)**	**1/5 (20.00%)**
General disorders		
Oedema peripheral † 1		
# participants affected / at risk	**0/5 (0.00%)**	**1/5 (20.00%)**
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	**0/5 (0.00%)**	**1/5 (20.00%)**
Otitis media chronic † 1		
# participants affected / at risk	**1/5 (20.00%)**	**0/5 (0.00%)**
Urinary tract infection † 1		
# participants affected / at risk	**0/5 (0.00%)**	**2/5 (40.00%)**
Injury, poisoning and procedural complications		
Upper limb fracture † 1		
# participants affected / at risk	**0/5 (0.00%)**	**1/5 (20.00%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**0/5 (0.00%)**	**1/5 (20.00%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**0/5 (0.00%)**	**1/5 (20.00%)**

† 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:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00434590 History of Changes
Other Study ID Numbers:	**CERL080AIT09**
Study First Received:	February 12, 2007
Results First Received:	December 13, 2010
Last Updated:	March 8, 2011
Health Authority:	Italy: The Italian Medicines Agency