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Trial record **1 of 1** for: CERL080AGB03

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Enteric-Coated Mycophenolate Sodium on Quality of Life in Patients With Gastrointestinal Symptoms Related to Mycophenolate Mofetil Therapy After Kidney Transplantation

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00239005

First received: October 12, 2005
Last updated: February 23, 2011
Last verified: February 2011
History of Changes

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Results First Received: December 8, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Renal Transplant
Interventions:	Drug: Enteric-Coated Mycophenolate Sodium (EC-MPS) Drug: Mycophenolate Mofetil (MMF)

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
In total, 135 patients were screened. One patient was not randomized due to an SAE prior to the randomization visit. Out of 134 randomized patients, 5 withdrew before taking study drug. Analysis population: 68 in EC-MPS, 61 in MMF.

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
Enteric-Coated Mycophenolate Sodium (EC-MPS)	Oral film-coated gastroresistant tablets containing 360mg or 180mg of mycophenolate sodium. Daily dose decided by the physician, was taken morning and evening.
Mycophenolate Mofetil (MMF)	250 mg capsules or 500 mg tablets of mycophenolate mofetil. Daily dose decided by physician, was taken morning and evening.

Participant Flow: Overall Study

	Enteric-Coated Mycophenolate Sodium (EC-MPS)	**Mycophenolate Mofetil (MMF)**
STARTED	**69**	**65**

Intention-to-treat Population (ITT)	**68**	**61**
COMPLETED	**57**	**53**
NOT COMPLETED	**12**	**12**
Adverse Event	**6**	**6**
Withdrawal by Subject	**3**	**4**
Unsatisfactory Therapeutic effect	**2**	**0**
Protocol Violation	**1**	**0**
Subj. cond. no longer needs study drug	**0**	**1**
Lost to Follow-up	**0**	**1**
Death	**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
Enteric-Coated Mycophenolate Sodium (EC-MPS)	Oral film-coated gastroresistant tablets containing 360mg or 180mg of mycophenolate sodium. Daily dose decided by the physician, was taken morning and evening.
Mycophenolate Mofetil (MMF)	250 mg capsules or 500 mg tablets of mycophenolate mofetil. Daily dose decided by physician, was taken morning and evening.
Total	Total of all reporting groups

Baseline Measures

	Enteric-Coated Mycophenolate Sodium (EC-MPS)	Mycophenolate Mofetil (MMF)	Total
Number of Participants [units: participants]	**68**	**61**	**129**
Age, Customized [1] **[units: participants]**			
<65 years	**65**	**51**	**116**
>=65 years	**3**	**10**	**13**
Gender [units: Participants]			
Female	**31**	**25**	**56**
Male	**37**	**36**	**73**

[1] Baseline Measures are based on Intention to treat (ITT) population.

Outcome Measures

Hide All Outcome Measures

1. Primary: Mycophenolic Acid (MPA) Maintenance Treatment [Time Frame: at week 13 (last visit)]

Measure Type	Primary
Measure Title	Mycophenolic Acid (MPA) Maintenance Treatment
Measure Description	The primary assessment was based on the percentage of patients who were maintained at week 13 on a dose at least one dose equivalent greater than at baseline (visit 2/week 1). A dose equivalent was defined as EC-MPS 180 mg/day or MMF 250 mg/day.
Time Frame	at week 13 (last visit)
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 intent-to-treat (ITT) population consisted of all randomized patients who provided baseline and at least 1 post-baseline assessment of the primary variable.

Reporting Groups

	Description
Enteric-Coated Mycophenolate Sodium (EC-MPS)	Oral film-coated gastroresistant tablets containing 360mg or 180mg of mycophenolate sodium. Daily dose decided by the physician, was taken morning and evening.
Mycophenolate Mofetil (MMF)	250 mg capsules or 500 mg tablets of mycophenolate mofetil. Daily dose decided by physician, was taken morning and evening.

Measured Values

	Enteric-Coated Mycophenolate Sodium (EC-MPS)	**Mycophenolate Mofetil (MMF)**
Number of Participants Analyzed [units: participants]	**68**	**61**
Mycophenolic Acid (MPA) Maintenance Treatment [units: Percentage of Patients] Number (95% Confidence Interval)	**47.06 (34.83 to 59.55)**	**16.39 (8.15 to 28.09)**

No statistical analysis provided for Mycophenolic Acid (MPA) Maintenance Treatment

2. Secondary: Changes in Gastrointestinal (GI) Symptoms as Measured by the Gastrointestinal Symptom Rating Scale (GSRS). [Time Frame: At week 3 and week 13 (last visit)]

Measure Type	Secondary
Measure Title	Changes in Gastrointestinal (GI) Symptoms as Measured by the Gastrointestinal Symptom Rating Scale (GSRS).
Measure Description	The GSRS is a 15-item instrument designed to assess the impact of upper and lower GI symptoms. There are five subscales: reflux, diarrhea, constipation, abdominal pain, and indigestion—each of which produces a mean subscale score ranging from 1 (no discomfort) to 7 (very severe discomfort). A higher score represents greater impairment of quality of life due to GI symptoms (range from 1 to 7).
Time Frame	At week 3 and week 13 (last visit)
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.
Intention to treat (ITT) population consisted of all randomized patients who provided baseline and at least 1 post-baseline assessment of the

primary variable. In this analysis patients who completed GSRS questionnaire in visit 2 (week 1), visit 3 (week 3) and visit 4 (week 13) were included.

Reporting Groups

	Description
Enteric-Coated Mycophenolate Sodium (EC-MPS)	Oral film-coated gastroresistant tablets containing 360mg or 180mg of mycophenolate sodium. Daily dose decided by the physician, was taken morning and evening.
Mycophenolate Mofetil (MMF)	250 mg capsules or 500 mg tablets of mycophenolate mofetil. Daily dose decided by physician, was taken morning and evening.

Measured Values

	Enteric-Coated Mycophenolate Sodium (EC-MPS)	Mycophenolate Mofetil (MMF)
Number of Participants Analyzed [units: participants]	**61**	**59**
Changes in Gastrointestinal (GI) Symptoms as Measured by the Gastrointestinal Symptom Rating Scale (GSRS). [units: Units on a scale] Least Squares Mean (Standard Error)		
Week 3: change in GSRS Total Score (N= 61, 59)	**-0.63 (0.139)**	**-0.32 (0.142)**
Week 13: change in GSRS Total Score (N= 60, 56)	**-0.44 (0.165)**	**-0.25 (0.169)**

No statistical analysis provided for Changes in Gastrointestinal (GI) Symptoms as Measured by the Gastrointestinal Symptom Rating Scale (GSRS).

3. Secondary: Changes in Gastrointestinal Symptoms as Measured by the Gastrointestinal Quality of Life Index (GIQLI). [Time Frame: At week 3 and week 13 (last visit)]

Measure Type	Secondary
Measure Title	Changes in Gastrointestinal Symptoms as Measured by the Gastrointestinal Quality of Life Index (GIQLI).
Measure Description	Health-related quality of life (HRQoL)was assessed by the Gastrointestinal Quality of Life Index (GIQLI). The GIQLI is a 36-item questionnaire to assess the impact of GI disease on daily life. The GIQLI also has five different subscales (GI symptoms, emotional status, physical and social functions, and stress of medical treatment) producing a total score of the 36 items. Lower scores represent more dysfunction. A higher score represents a better quality of life (range from 0 to 144).
Time Frame	At week 3 and week 13 (last visit)
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.
Intention to treat (ITT) population consisted of all randomized patients who provided baseline and at least 1 post-baseline assessment of the primary variable. In this analysis patients who completed GIQLI questionnaire in visit 2 (week 1), visit 3 (week 3) and visit 4 (week 13) were included.

Reporting Groups

	Description
Enteric-Coated Mycophenolate Sodium (EC-MPS)	Oral film-coated gastroresistant tablets containing 360mg or 180mg of mycophenolate sodium. Daily dose decided by the physician, was taken morning and evening.
Mycophenolate Mofetil (MMF)	250 mg capsules or 500 mg tablets of mycophenolate mofetil. Daily dose decided by physician, was taken morning and evening.

Measured Values

	Enteric-Coated Mycophenolate Sodium (EC-MPS)	Mycophenolate Mofetil (MMF)
Number of Participants Analyzed [units: participants]	**61**	**58**
Changes in Gastrointestinal Symptoms as Measured by the Gastrointestinal Quality of Life Index (GIQLI). [units: Units on a scale] Least Squares Mean (Standard Error)		
Week 3: change in GIQLI Total Score (N= 61, 58)	**11.65 (3.470)**	**6.08 (3.549)**
Week 13: change in GIQLI Total Score (N= 60, 56)	**4.84 (4.331)**	**1.77 (4.458)**

No statistical analysis provided for Changes in Gastrointestinal Symptoms as Measured by the Gastrointestinal Quality of Life Index (GIQLI).

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	13 weeks
Additional Description	The Safety population consisted of all randomized patients who had at least one post-baseline safety assessment.

Reporting Groups

	Description
Enteric-Coated Mycophenolate Sodium (EC-MPS)	Oral film-coated gastroresistant tablets containing 360mg or 180mg of mycophenolate sodium. Daily dose decided by the physician, was taken morning and evening.
Mycophenolate Mofetil (MMF)	250 mg capsules or 500 mg tablets of mycophenolate mofetil. Daily dose decided by physician, was taken morning and evening.

Serious Adverse Events

	Enteric-Coated Mycophenolate Sodium (EC-MPS)	Mycophenolate Mofetil (MMF)
Total, serious adverse events		
# participants affected / at risk	**9/68 (13.24%)**	**7/61 (11.48%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**
Cardiac disorders		
Cardiac failure congestive † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
Gastrointestinal disorders		
Abdominal pain upper † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**
Diarrhoea † 1		
# participants affected / at risk	**1/68 (1.47%)**	**1/61 (1.64%)**
Gastritis † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**

Nausea † 1		
# participants affected / at risk	**1/68 (1.47%)**	**1/61 (1.64%)**
Vomiting † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
General disorders		
Chest pain † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**
Chills † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**
Pyrexia † 1		
# participants affected / at risk	**3/68 (4.41%)**	**0/61 (0.00%)**
Infections and infestations		
Cytomegalovirus infection † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
Lower respiratory tract infection † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**
Pneumonia † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
Sepsis † 1		
# participants affected / at risk	**0/68 (0.00%)**	**2/61 (3.28%)**
Urinary tract infection † 1		
# participants affected / at risk	**2/68 (2.94%)**	**1/61 (1.64%)**
Injury, poisoning and procedural complications		
Complications of transplanted kidney † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**
Hyperkalaemia † 1		
# participants affected / at risk	**1/68 (1.47%)**	**1/61 (1.64%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**0/68 (0.00%)**	**1/61 (1.64%)**
Renal and urinary disorders		
Renal failure acute † 1		
# participants affected / at risk	**1/68 (1.47%)**	**0/61 (0.00%)**
Respiratory, thoracic and mediastinal disorders		

Dyspnoea † 1		
# participants affected / at risk	0/68 (0.00%)	1/61 (1.64%)
Vascular disorders		
Aortic dissection † 1		
# participants affected / at risk	0/68 (0.00%)	1/61 (1.64%)

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	13 weeks
Additional Description	The Safety population consisted of all randomized patients who had at least one post-baseline safety assessment.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Mycophenolate Mofetil (MMF)	250 mg capsules or 500 mg tablets of mycophenolate mofetil. Daily dose decided by physician, was taken morning and evening.

Other Adverse Events

	Enteric-Coated Mycophenolate Sodium (EC-MPS)	Mycophenolate Mofetil (MMF)
Total, other (not including serious) adverse events		
# participants affected / at risk	25/68 (36.76%)	26/61 (42.62%)
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	4/68 (5.88%)	1/61 (1.64%)
Diarrhoea † 1		
# participants affected / at risk	12/68 (17.65%)	12/61 (19.67%)
Dyspepsia † 1		
# participants affected / at risk	3/68 (4.41%)	5/61 (8.20%)
Nausea † 1		
# participants affected / at risk	3/68 (4.41%)	4/61 (6.56%)
Vomiting † 1		
# participants affected / at risk	5/68 (7.35%)	4/61 (6.56%)
Infections and infestations		
Lower respiratory tract infection † 1		
# participants affected / at risk	2/68 (2.94%)	4/61 (6.56%)
Nasopharyngitis † 1		
# participants affected / at risk	4/68 (5.88%)	4/61 (6.56%)

Urinary tract infection † 1		
# participants affected / at risk	**2/68 (2.94%)**	**4/61 (6.56%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**4/68 (5.88%)**	**1/61 (1.64%)**

† 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:	NCT00239005 History of Changes
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