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Trial record **1 of 1** for: CERL080ADE09

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Measurement of Gastrointestinal (GI) and Health-related Quality of Life (HRQL) Outcomes in Liver Transplant Recipients

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00405652

First received: November 27, 2006
Last updated: February 8, 2011
Last verified: February 2011
History of Changes

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Results First Received: December 1, 2010

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Liver Transplantation
Intervention:	Drug: Enteric-coated Mycophenolate sodium (EC-MPS)

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
Enteric-coated Mycophenolate Sodium	Enteric-coated Mycophenolate sodium (EC-MPS), administered orally twice a day to achieve a dose equimolar to the dose of Mycophenolate mofetil (MMF) the patient was taking at the time of study entry up to a maximum dose of 1440 mg.

Participant Flow: Overall Study

	Enteric-coated Mycophenolate Sodium
STARTED	**34**
COMPLETED	**30**

NOT COMPLETED	**4**
Adverse Event	**4**

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	Enteric-coated Mycophenolate sodium (EC-MPS), administered orally twice a day to achieve a dose equimolar to the dose of Mycophenolate mofetil (MMF) the patient was taking at the time of study entry up to a maximum dose of 1440 mg.

Baseline Measures

	Enteric-coated Mycophenolate Sodium
Number of Participants [units: participants]	**34**
Age [units: years] Mean (Standard Deviation)	**55.8 (9.6)**
Gender [units: participants]	
Female	**14**
Male	**20**

Outcome Measures

Hide All Outcome Measures

1. Primary: Changes in Gastrointestinal Symptom Severity and Health Related Quality of Life [Time Frame: Baseline, End of Study (6-8 weeks)]

Measure Type	Primary
Measure Title	Changes in Gastrointestinal Symptom Severity and Health Related Quality of Life
Measure Description	Change in Gastrointestinal symptom rating scale (GSRS) total score from baseline visit to follow-up visit 6-8 weeks after treatment. The GSRS has 5 subscales (reflux, diarrhea, constipation, abdominal pain, and indigestion) producing a mean subscale score ranging from 1 (no discomfort) to 7 (very severe discomfort). The GSRS total score was computed by the mean of the subscale scores.
Time Frame	Baseline, End of Study (6-8 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.
Intent to Treat Population (No last Observation Carried Forward). The number of participants completing the GSRS at Baseline = 31 and at

the End of Study= 29.

Reporting Groups

	Description
Enteric-coated Mycophenolate Sodium	Enteric-coated Mycophenolate sodium (EC-MPS), administered orally twice a day to achieve a dose equimolar to the dose of Mycophenolate mofetil (MMF) the patient was taking at the time of study entry up to a maximum dose of 1440 mg.

Measured Values

	Enteric-coated Mycophenolate Sodium
Number of Participants Analyzed [units: participants]	**31**
Changes in Gastrointestinal Symptom Severity and Health Related Quality of Life [units: Scores on a Scale] Mean (Standard Deviation)	
Baseline (Visit 1) n=31	**2.88 (0.66)**
End of Study (Visit 2) n=29	**2.10 (0.78)**

No statistical analysis provided for Changes in Gastrointestinal Symptom Severity and Health Related Quality of Life

2. Secondary: The Number of Participants With Subclinical Rejection as Evaluated by a Change in Liver Enzymes [Time Frame: 12-20 weeks]

Measure Type	Secondary
Measure Title	The Number of Participants With Subclinical Rejection as Evaluated by a Change in Liver Enzymes
Measure Description	The number of participants with subclinical rejection episodes as defined by a steroid-sensitive, clinically relevant increase of AST, ALT, gamma-GT, AP or bilirubin (i.e., elevation of one or more of these enzymes that was considered clinically relevant and showed resolution upon treatment with a slight increase of steroid dosage).
Time Frame	12-20 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.
Intent to Treat

Reporting Groups

	Description
Enteric-coated Mycophenolate Sodium	Enteric-coated Mycophenolate sodium (EC-MPS), administered orally twice a day to achieve a dose equimolar to the dose of Mycophenolate mofetil (MMF) the patient was taking at the time of study entry up to a maximum dose of 1440 mg.

Measured Values

	Enteric-coated Mycophenolate Sodium
Number of Participants Analyzed [units: participants]	**34**
The Number of Participants With Subclinical Rejection as Evaluated by a Change in Liver Enzymes [units: Participants]	**6**

No statistical analysis provided for The Number of Participants With Subclinical Rejection as Evaluated by a Change in Liver Enzymes

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Enteric-coated Mycophenolate Sodium	Enteric-coated Mycophenolate sodium (EC-MPS), administered orally twice a day to achieve a dose equimolar to the dose of Mycophenolate mofetil (MMF) the patient was taking at the time of study entry up to a maximum dose of 1440 mg.

Serious Adverse Events

	Enteric-coated Mycophenolate Sodium
Total, serious adverse events	
# participants affected / at risk	**4/34 (11.76%)**
Gastrointestinal disorders	
Faecaloma † 1	
# participants affected / at risk	**1/34 (2.94%)**
Infections and infestations	
Hepatitis c † 1	
# participants affected / at risk	**1/34 (2.94%)**
Herpes zoster † 1	
# participants affected / at risk	**1/34 (2.94%)**
Injury, poisoning and procedural complications	
Transplant failure † 1	
# participants affected / at risk	**1/34 (2.94%)**
Investigations	
Alanine aminotransferase increased † 1	
# participants affected / at risk	**1/34 (2.94%)**
Aspartate aminotransferase increased † 1	
# participants affected / at risk	**1/34 (2.94%)**
Blood alkaline phosphatase increased † 1	
# participants affected / at risk	**1/34 (2.94%)**
Gamma-glutamyltransferase increased † 1	
# participants affected / at risk	**1/34 (2.94%)**
Glutamate dehydrogenase increased † 1	
# participants affected / at risk	**1/34 (2.94%)**
Psychiatric disorders	
Alcoholism † 1	
# participants affected / at risk	**1/34 (2.94%)**

Renal and urinary disorders	
Renal failure † 1	
# participants affected / at risk	**1/34 (2.94%)**
Skin and subcutaneous tissue disorders	
Pruritus generalised † 1	
# participants affected / at risk	**1/34 (2.94%)**

† 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
Enteric-coated Mycophenolate Sodium	Enteric-coated Mycophenolate sodium (EC-MPS), administered orally twice a day to achieve a dose equimolar to the dose of Mycophenolate mofetil (MMF) the patient was taking at the time of study entry up to a maximum dose of 1440 mg.

Other Adverse Events

	Enteric-coated Mycophenolate Sodium
Total, other (not including serious) adverse events	
# participants affected / at risk	**23/34 (67.65%)**
Gastrointestinal disorders	
Abdominal distension † 1	
# participants affected / at risk	**11/34 (32.35%)**
Abdominal pain † 1	
# participants affected / at risk	**7/34 (20.59%)**
Constipation † 1	
# participants affected / at risk	**3/34 (8.82%)**
Diarrhoea † 1	
# participants affected / at risk	**10/34 (29.41%)**
Dyspepsia † 1	
# participants affected / at risk	**3/34 (8.82%)**
Nausea † 1	
# participants affected / at risk	**5/34 (14.71%)**
General disorders	
Fatigue † 1	
# participants affected / at risk	**2/34 (5.88%)**
Feeling cold † 1	

# participants affected / at risk	**2/34 (5.88%)**
Infections and infestations	
Nasopharyngitis † 1	
# participants affected / at risk	**4/34 (11.76%)**
Investigations	
Alanine aminotransferase increased † 1	
# participants affected / at risk	**2/34 (5.88%)**
Blood alkaline phosphatase increased † 1	
# participants affected / at risk	**2/34 (5.88%)**
Blood bilirubin increased † 1	
# participants affected / at risk	**3/34 (8.82%)**
Gamma-glutamyltransferase increased † 1	
# participants affected / at risk	**3/34 (8.82%)**
Nervous system disorders	
Headache † 1	
# participants affected / at risk	**3/34 (8.82%)**
Respiratory, thoracic and mediastinal disorders	
Cough † 1	
# participants affected / at risk	**2/34 (5.88%)**
Skin and subcutaneous tissue disorders	
Pruritus † 1	
# participants affected / at risk	**2/34 (5.88%)**

† 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
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