Trial record **1 of 1** for: CERL080ADE12
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Intensified vs. Standard Dose Therapy With Mycophenolate Sodium Plus Cyclosporin Microemulsion and Corticosteroid Combination in Patients With de Novo Renal Transplant Patients

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00369278

First received: August 25, 2006
Last updated: March 25, 2011
Last verified: March 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: December 15, 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 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
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study(month 6): 1440 mg/day (2 x 720 mg)

Participant Flow: Overall Study

	Intensified Mycophenolate Sodium	**Standard Mycophenolate Sodium**
STARTED	**63**	**65**

COMPLETED	**39**	**44**
NOT COMPLETED	**24**	**21**
Adverse Event	**14**	**11**
Unsatisfactory therapeutic effect	**4**	**5**
Protocol Violation	**2**	**1**
Withdrawal by Subject	**2**	**2**
Lost to Follow-up	**1**	**0**
Graft loss	**1**	**2**

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
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study(month 6): 1440 mg/day (2 x 720 mg)
Total	Total of all reporting groups

Baseline Measures

	Intensified Mycophenolate Sodium	**Standard Mycophenolate Sodium**	**Total**
Number of Participants [units: participants]	**63**	**65**	**128**
Age [units: years] Mean (Standard Deviation)	**52.4 (12.5)**	**50.4 (14.6)**	**51.4 (13.6)**
Gender [units: participants]			
Female	**29**	**30**	**59**
Male	**34**	**35**	**69**

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to First Occurrence of a Mycophenolic Acid (MPA) Plasma Concentration of ≥ 40 mg*h/L [Time Frame: Assessed on day 3, 10, 21, 42, 56 and 84]

Measure Type	Primary
Measure Title	Time to First Occurrence of a Mycophenolic Acid (MPA) Plasma Concentration of ≥ 40 mg*h/L

Measure Description	Non-compartmental MPA pharmacokinetic parameters were derived from individual plasma concentration-time profiles using WinNonLin 5.2 software. The areas under the curve were calculated by means of the linear trapezoidal rule.
Time Frame	Assessed on day 3, 10, 21, 42, 56 and 84
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.
Pharmacokinetic profiles were performed only in patients involved in Phase I of the study. The pharmacokinetic population consisted of 42 participants.

Reporting Groups

	Description
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study(month 6): 1440 mg/day (2 x 720 mg)

Measured Values

	Intensified Mycophenolate Sodium	**Standard Mycophenolate Sodium**
Number of Participants Analyzed [units: participants]	**23**	**19**
Time to First Occurrence of a Mycophenolic Acid (MPA) Plasma Concentration of ≥ 40 mg*h/L [units: Days] Median (95% Confidence Interval)	**7.00 (5.0 to 23.0)**	**43.00 (12.0 to 58.0)**

No statistical analysis provided for Time to First Occurrence of a Mycophenolic Acid (MPA) Plasma Concentration of ≥ 40 mg*h/L

2. Primary: Number of Participants With Any Treatment Failure [Time Frame: 6 months]

Measure Type	Primary
Measure Title	Number of Participants With Any Treatment Failure
Measure Description	Treatment failures were defined as a composite endpoint of biopsy proven acute rejection (BPAR), graft loss, and death, loss to follow up and discontinuations from study drug treatment due to lack of efficacy or toxicity (at least one condition must be present) during the first 6 months or until final assessment. Any participants who were suspected of having acute rejection episodes had biopsies performed to prove whether a rejection had occurred. Graft loss was considered as the day the patient started dialysis and was not able to subsequently be removed or the day of graft nephrectomy.
Time Frame	6 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.
No text entered.

Reporting Groups

	Description
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study(month 6): 1440 mg/day (2 x 720 mg)

Measured Values

	Intensified Mycophenolate Sodium	Standard Mycophenolate Sodium
Number of Participants Analyzed [units: participants]	**63**	**65**
Number of Participants With Any Treatment Failure [units: Participants]	**19**	**24**

No statistical analysis provided for Number of Participants With Any Treatment Failure

3. Secondary: Number of Participants With Single Treatment Failures [Time Frame: 6 months]

Measure Type	Secondary
Measure Title	Number of Participants With Single Treatment Failures
Measure Description	Rates for all individual components of the primary endpoint 'treatment failure' until day 180: • Acute rejection diagnosed by biopsy (BPAR) • graft loss • death • loss to follow up • discontinuation from study drug due to lack of efficacy or toxicity (adverse events, every adverse event had to be interpreted as toxicity) • conversion to another dosing regimen (conversion to tacrolimus, prograf, etc.)
Time Frame	6 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.
Intent-to-treat population

Reporting Groups

	Description
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study(month 6): 1440 mg/day (2 x 720 mg)

Measured Values

	Intensified Mycophenolate Sodium	Standard Mycophenolate Sodium
Number of Participants Analyzed [units: participants]	**63**	**65**
Number of Participants With Single Treatment Failures		

[units: Participants]		
Biopsy-proven acute rejection	2	11
Graft loss	1	2
Death	0	0
Loss to follow-up	1	0
Discontinuation due to lack of efficacy / toxicity	17	15
Conversion of doses	8	10
Treated rejections	13	24

No statistical analysis provided for Number of Participants With Single Treatment Failures

4. Secondary: Renal Function as Measured by Serum Creatinine [Time Frame: 6 months]

Measure Type	Secondary
Measure Title	Renal Function as Measured by Serum Creatinine
Measure Description	No text entered.
Time Frame	6 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.
No text entered.

Reporting Groups

	Description
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study(month 6): 1440 mg/day (2 x 720 mg)

Measured Values

	Intensified Mycophenolate Sodium	Standard Mycophenolate Sodium
Number of Participants Analyzed [units: participants]	63	65
Renal Function as Measured by Serum Creatinine [units: mg/dL] Mean (Standard Deviation)		
Baseline	8.0 (2.7)	7.8 (2.9)
End of study	2.2 (1.5)	2.6 (2.2)

No statistical analysis provided for Renal Function as Measured by Serum Creatinine

5. Secondary: Renal Function as Measured by Glomerular Filtration Rate (GFR) [Time Frame: 6 months]

Measure Type	Secondary
Measure Title	Renal Function as Measured by Glomerular Filtration Rate (GFR)
Measure Description	The Glomerular Filtration Rate (GFR) was calculated using the following formulas: • Cockcroft-Gault formula: calculation using the participant's age, gender, weight, and serum creatinine levels. • MDRD formula: calculation using the participant's age, gender, serum creatinine, urea nitrogen, and albumin levels.
Time Frame	6 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.
Intent-to-treat population for whom data was available. End of Study data was imputed using Last Observation Carried Forward (LOCF).

Reporting Groups

	Description
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study(month 6): 1440 mg/day (2 x 720 mg)

Measured Values

	Intensified Mycophenolate Sodium	**Standard Mycophenolate Sodium**
Number of Participants Analyzed [units: participants]	**63**	**65**
Renal Function as Measured by Glomerular Filtration Rate (GFR) **[units: ml/min]** **Mean (Standard Deviation)**		
MDRD formula: Baseline [n=44, 56]	**9.0 (3.9)**	**9.4 (3.9)**
MDRD formula: End of study [n=61, 64]	**41.1 (17.1)**	**40.6 (24.8)**
Cockcroft-Gault formula: Baseline [n=61, 65]	**12.1 (4.8)**	**12.0 (5.0)**
Cockcroft-Gault formula: End of study [n=63, 65]	**52.4 (23.9)**	**47.9 (27.1)**

No statistical analysis provided for Renal Function as Measured by Glomerular Filtration Rate (GFR)

6. Primary: Time to First Occurrence of Any Treatment Failure During the First 6 Months Post-treatment or at Month 6 Post-treatment [Time Frame: 6 months]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

7. Secondary: Rates of Events for Treated Acute Rejection, Death, Graft Loss, or Loss to Follow up on Day 28, Day 84, and Day 180 [Time Frame: 6 months]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

8. Secondary: Time to “Event” for the Composite Endpoint as Well as All Individual Components of That Endpoint “Treatment Failure” Including Clinical Rejections [Time Frame: 6 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
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study (month 6): 1440 mg/day (2 x 720 mg)

Serious Adverse Events

	Intensified Mycophenolate Sodium	Standard Mycophenolate Sodium
Total, serious adverse events		
# participants affected / at risk	**44/63 (69.84%)**	**40/65 (61.54%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**2/63 (3.17%)**	**0/65 (0.00%)**
Disseminated intravascular coagulation † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Leukopenia † 1		
# participants affected / at risk	**1/63 (1.59%)**	**1/65 (1.54%)**
Cardiac disorders		
Myocardial infarction † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Supraventricular tachycardia † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Tricuspid valve incompetence † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Wolff-Parkinson-White syndrome † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**2/63 (3.17%)**	**0/65 (0.00%)**
Diarrhoea † 1		
# participants affected / at risk	**4/63 (6.35%)**	**1/65 (1.54%)**
Duodenal ulcer † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Duodenitis † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Gastritis † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**

Gastrointestinal haemorrhage † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Ileus † 1		
# participants affected / at risk	**0/63 (0.00%)**	**2/65 (3.08%)**
Inguinal hernia † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Inguinal hernia, obstructive † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Intra-abdominal haematoma † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Intra-abdominal haemorrhage † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Large intestine perforation † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Nausea † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Pancreatitis acute † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Reflux oesophagitis † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Small intestinal perforation † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Vomiting † 1		
# participants affected / at risk	**1/63 (1.59%)**	**1/65 (1.54%)**
General disorders		
Catheter related complication † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Impaired healing † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Multi-organ failure † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Oedema peripheral † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Pyrexia † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Immune system disorders		
Transplant rejection † 1		
# participants affected / at risk	**0/63 (0.00%)**	**2/65 (3.08%)**
Infections and infestations		
Abdominal abscess † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Clostridium difficile colitis † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Cytomegalovirus gastritis † 1		

# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Cytomegalovirus infection † 1		
# participants affected / at risk	2/63 (3.17%)	1/65 (1.54%)
Enterococcal infection † 1		
# participants affected / at risk	1/63 (1.59%)	1/65 (1.54%)
Escherichia bacteraemia † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Gastroenteritis † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Gastroenteritis clostridial † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Gastroenteritis norovirus † 1		
# participants affected / at risk	2/63 (3.17%)	1/65 (1.54%)
Gastrointestinal infection † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Haematoma infection † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Human polyomavirus infection † 1		
# participants affected / at risk	1/63 (1.59%)	1/65 (1.54%)
Infected lymphocele † 1		
# participants affected / at risk	0/63 (0.00%)	2/65 (3.08%)
Infection † 1		
# participants affected / at risk	2/63 (3.17%)	1/65 (1.54%)
Oesophageal candidiasis † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Otitis media † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Perinephric abscess † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Pneumonia † 1		
# participants affected / at risk	4/63 (6.35%)	0/65 (0.00%)
Renal abscess † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Renal cyst infection † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Respiratory tract infection † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Sepsis † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Staphylococcal infection † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Tracheobronchitis † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Upper respiratory tract infection † 1		

# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Urinary tract infection † 1		
# participants affected / at risk	5/63 (7.94%)	9/65 (13.85%)
Urosepsis † 1		
# participants affected / at risk	1/63 (1.59%)	4/65 (6.15%)
Wound abscess † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Wound infection † 1		
# participants affected / at risk	2/63 (3.17%)	0/65 (0.00%)
Wound infection bacterial † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Wound infection staphylococcal † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Injury, poisoning and procedural complications		
Anastomotic leak † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Arteriovenous graft thrombosis † 1		
# participants affected / at risk	2/63 (3.17%)	0/65 (0.00%)
Clavicle fracture † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Complications of transplanted kidney † 1		
# participants affected / at risk	2/63 (3.17%)	3/65 (4.62%)
Femoral neck fracture † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Foot fracture † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Graft loss † 1		
# participants affected / at risk	2/63 (3.17%)	2/65 (3.08%)
Incisional hernia † 1		
# participants affected / at risk	1/63 (1.59%)	1/65 (1.54%)
Perirenal haematoma † 1		
# participants affected / at risk	0/63 (0.00%)	2/65 (3.08%)
Post procedural urine leak † 1		
# participants affected / at risk	2/63 (3.17%)	1/65 (1.54%)
Seroma † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Shunt aneurysm † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Thoracic vertebral fracture † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Transplant failure † 1		
# participants affected / at risk	0/63 (0.00%)	5/65 (7.69%)
Wound dehiscence † 1		
# participants affected / at risk	1/63 (1.59%)	1/65 (1.54%)

Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	**9/63 (14.29%)**	**6/65 (9.23%)**
Haemoglobin decreased † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Metabolism and nutrition disorders		
Calciphylaxis † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Dehydration † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Hyperglycaemia † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Hypervolaemia † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Nervous system disorders		
Cerebral infarction † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Cerebrovascular accident † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Migraine † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Transient ischaemic attack † 1		
# participants affected / at risk	**1/63 (1.59%)**	**1/65 (1.54%)**
Uraemic encephalopathy † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Psychiatric disorders		
Delirium † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Depression † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Hallucination, visual † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Renal and urinary disorders		
Haematuria † 1		
# participants affected / at risk	**0/63 (0.00%)**	**1/65 (1.54%)**
Renal artery occlusion † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Renal artery stenosis † 1		
# participants affected / at risk	**2/63 (3.17%)**	**0/65 (0.00%)**
Renal failure † 1		
# participants affected / at risk	**1/63 (1.59%)**	**0/65 (0.00%)**
Renal failure acute † 1		
# participants affected / at risk	**4/63 (6.35%)**	**5/65 (7.69%)**
Ureteral necrosis † 1		

# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Urinary retention † 1		
# participants affected / at risk	2/63 (3.17%)	1/65 (1.54%)
Urinary tract obstruction † 1		
# participants affected / at risk	1/63 (1.59%)	1/65 (1.54%)
Urinoma † 1		
# participants affected / at risk	1/63 (1.59%)	2/65 (3.08%)
Vesicoureteric reflux † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Pelvic congestion † 1		
# participants affected / at risk	2/63 (3.17%)	2/65 (3.08%)
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Dyspnoea † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Pneumothorax † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Skin and subcutaneous tissue disorders		
Skin inflammation † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Surgical and medical procedures		
Pneumatic compression therapy † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Wound treatment † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	0/63 (0.00%)	2/65 (3.08%)
Femoral arterial stenosis † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Haematoma † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Hypertension † 1		
# participants affected / at risk	2/63 (3.17%)	1/65 (1.54%)
Lymphocele † 1		
# participants affected / at risk	4/63 (6.35%)	3/65 (4.62%)
Peripheral artery aneurysm † 1		

# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Peripheral artery dissection † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)
Shock † 1		
# participants affected / at risk	0/63 (0.00%)	1/65 (1.54%)
Shock haemorrhagic † 1		
# participants affected / at risk	1/63 (1.59%)	0/65 (0.00%)

† 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
Intensified Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1-14: 2880 mg/day (2 x 1440 mg), then day 15-42: 2160 mg/day (2 x 1080 mg), then day 43-End of study (month 6): 1440 mg/day (2 x 720 mg)
Standard Mycophenolate Sodium	Enteric-coated mycophenolate sodium was given according to the following dosing regimen: Day 1 - End of Study (month 6): 1440 mg/day (2 x 720 mg)

Other Adverse Events

	Intensified Mycophenolate Sodium	Standard Mycophenolate Sodium
Total, other (not including serious) adverse events		
# participants affected / at risk	62/63 (98.41%)	63/65 (96.92%)
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	16/63 (25.40%)	19/65 (29.23%)
Leukopenia † 1		
# participants affected / at risk	12/63 (19.05%)	14/65 (21.54%)
Thrombocytopenia † 1		
# participants affected / at risk	4/63 (6.35%)	1/65 (1.54%)
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	11/63 (17.46%)	5/65 (7.69%)
Constipation † 1		
# participants affected / at risk	19/63 (30.16%)	15/65 (23.08%)
Diarrhoea † 1		
# participants affected / at risk	19/63 (30.16%)	23/65 (35.38%)

Dyspepsia † 1		
# participants affected / at risk	4/63 (6.35%)	0/65 (0.00%)
Flatulence † 1		
# participants affected / at risk	13/63 (20.63%)	7/65 (10.77%)
Nausea † 1		
# participants affected / at risk	23/63 (36.51%)	19/65 (29.23%)
Vomiting † 1		
# participants affected / at risk	16/63 (25.40%)	16/65 (24.62%)
General disorders		
Oedema † 1		
# participants affected / at risk	16/63 (25.40%)	14/65 (21.54%)
Oedema peripheral † 1		
# participants affected / at risk	15/63 (23.81%)	16/65 (24.62%)
Pain † 1		
# participants affected / at risk	1/63 (1.59%)	4/65 (6.15%)
Pyrexia † 1		
# participants affected / at risk	3/63 (4.76%)	8/65 (12.31%)
Infections and infestations		
BK virus infection † 1		
# participants affected / at risk	4/63 (6.35%)	1/65 (1.54%)
Cytomegalovirus infection † 1		
# participants affected / at risk	2/63 (3.17%)	7/65 (10.77%)
Nasopharyngitis † 1		
# participants affected / at risk	3/63 (4.76%)	8/65 (12.31%)
Pneumonia † 1		
# participants affected / at risk	1/63 (1.59%)	7/65 (10.77%)
Rhinitis † 1		
# participants affected / at risk	4/63 (6.35%)	5/65 (7.69%)
Urinary tract infection † 1		
# participants affected / at risk	24/63 (38.10%)	26/65 (40.00%)
Injury, poisoning and procedural complications		
Complications of transplanted kidney † 1		
# participants affected / at risk	20/63 (31.75%)	22/65 (33.85%)
Procedural pain † 1		
# participants affected / at risk	3/63 (4.76%)	4/65 (6.15%)
Wound complication † 1		
# participants affected / at risk	9/63 (14.29%)	13/65 (20.00%)
Wound dehiscence † 1		
# participants affected / at risk	7/63 (11.11%)	9/65 (13.85%)
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	7/63 (11.11%)	12/65 (18.46%)
Blood glucose increased † 1		
# participants affected / at risk	5/63 (7.94%)	2/65 (3.08%)

C-reactive protein increased † 1		
# participants affected / at risk	7/63 (11.11%)	1/65 (1.54%)
Haemoglobin decreased † 1		
# participants affected / at risk	4/63 (6.35%)	1/65 (1.54%)
Weight increased † 1		
# participants affected / at risk	4/63 (6.35%)	1/65 (1.54%)
Metabolism and nutrition disorders		
Diabetes mellitus † 1		
# participants affected / at risk	5/63 (7.94%)	6/65 (9.23%)
Hypercholesterolaemia † 1		
# participants affected / at risk	7/63 (11.11%)	6/65 (9.23%)
Hyperkalaemia † 1		
# participants affected / at risk	9/63 (14.29%)	9/65 (13.85%)
Hyperphosphataemia † 1		
# participants affected / at risk	4/63 (6.35%)	6/65 (9.23%)
Hyperuricaemia † 1		
# participants affected / at risk	4/63 (6.35%)	5/65 (7.69%)
Hypocalcaemia † 1		
# participants affected / at risk	19/63 (30.16%)	14/65 (21.54%)
Hypokalaemia † 1		
# participants affected / at risk	23/63 (36.51%)	31/65 (47.69%)
Hypomagnesaemia † 1		
# participants affected / at risk	6/63 (9.52%)	5/65 (7.69%)
Hypophosphataemia † 1		
# participants affected / at risk	13/63 (20.63%)	10/65 (15.38%)
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	2/63 (3.17%)	5/65 (7.69%)
Muscle spasms † 1		
# participants affected / at risk	7/63 (11.11%)	1/65 (1.54%)
Pain in extremity † 1		
# participants affected / at risk	3/63 (4.76%)	5/65 (7.69%)
Nervous system disorders		
Headache † 1		
# participants affected / at risk	8/63 (12.70%)	9/65 (13.85%)
Tremor † 1		
# participants affected / at risk	4/63 (6.35%)	3/65 (4.62%)
Psychiatric disorders		
Sleep disorder † 1		
# participants affected / at risk	11/63 (17.46%)	12/65 (18.46%)
Renal and urinary disorders		
Bladder pain † 1		
# participants affected / at risk	6/63 (9.52%)	9/65 (13.85%)
Dysuria † 1		

# participants affected / at risk	**6/63 (9.52%)**	**3/65 (4.62%)**
Haematuria † 1		
# participants affected / at risk	**7/63 (11.11%)**	**5/65 (7.69%)**
Residual urine † 1		
# participants affected / at risk	**4/63 (6.35%)**	**1/65 (1.54%)**
Urinary retention † 1		
# participants affected / at risk	**6/63 (9.52%)**	**2/65 (3.08%)**
Urinary tract obstruction † 1		
# participants affected / at risk	**1/63 (1.59%)**	**7/65 (10.77%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**7/63 (11.11%)**	**7/65 (10.77%)**
Dyspnoea † 1		
# participants affected / at risk	**5/63 (7.94%)**	**8/65 (12.31%)**
Vascular disorders		
Haematoma † 1		
# participants affected / at risk	**0/63 (0.00%)**	**5/65 (7.69%)**
Hypertension † 1		
# participants affected / at risk	**10/63 (15.87%)**	**4/65 (6.15%)**
Hypotension † 1		
# participants affected / at risk	**8/63 (12.70%)**	**3/65 (4.62%)**
Lymphocele † 1		
# participants affected / at risk	**4/63 (6.35%)**	**14/65 (21.54%)**

† 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:	NCT00369278 History of Changes
Other Study ID Numbers:	**CERL080ADE12**
Study First Received:	August 25, 2006
Results First Received:	December 15, 2010
Last Updated:	March 25, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices