ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: CERL080A2419

Previous Study | Return to List | Next Study

Evaluation of the Therapeutic Benefit of an Initial Intensified Dosing Regimen of Mycophenolate Sodium Versus a Standard Regimen in Renal Transplant Patients

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00419926

First received: January 8, 2007
Last updated: February 25, 2011
Last verified: February 2011
History of Changes

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

Results First Received: December 14, 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
Interventions:	Drug: Enteric-coated mycophenolate sodium (Myfortic) Drug: Cyclosporine (Neoral) Drug: Prednisone

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 (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Participant Flow: Overall Study

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	Standard Mycophenolate Sodium (Myfortic) Dosing Regimen
STARTED	155 [1]	158 [2]
COMPLETED	141	148
NOT COMPLETED	14	10
Withdrawal by Subject	7	3
Administrative Problem	4	4
Lost to Follow-up	1	2
Death	2	1

[1] Intention to treat population, 150 is safety population.
[2] Intention to treat population, 154 is safety population.

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 (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.
Total	Total of all reporting groups

Baseline Measures

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	Total
Number of Participants [units: participants]	155	158	313
Age, Customized [units: participants]			
< 50 years	100	102	202
>=50 years	55	56	111
Gender [units: participants]			
Female	53	54	107
Male	102	104	206

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death [Time Frame: 6 months]

Measure Type	Primary
Measure Title	Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death
Measure Description	To evaluate therapeutic benefit by comparing the efficacy defined as the number of participants with treatment failure (biopsy-proven acute rejection [BPAR], graft loss [GFL] or death) at 6 months post-transplant. BPAR was defined as a biopsy graded IA, IB, IIA, IIB or III using Banff 2000 classification. A graft core biopsy was performed within 24 hours of initiation of anti-rejection therapy. GFL was defined as the day the allograft was presumed lost (the day the patient started dialysis, the day of nephrectomy or the day of irreversible graft loss demonstrated by imaging techniques.)
Time Frame	6 months
Safety Issue	Yes

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.

Reporting Groups

	Description
Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Measured Values

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	**Standard Mycophenolate Sodium (Myfortic) Dosing Regimen**
Number of Participants Analyzed [units: participants]	**155**	**158**
Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death [units: number of participants]	**33**	**36**

No statistical analysis provided for Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death

2. Primary: Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death [Time Frame: 6 months]

Measure Type	Primary
Measure Title	Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death

Measure Description	To evaluate therapeutic benefit by comparing the efficacy defined as the number of participants with treatment failure (biopsy-proven acute rejection [BPAR], graft loss [GFL] or death) at 6 months post-transplant. BPAR was defined as a biopsy graded IA, IB, IIA, IIB or III using Banff 2000 classification. A graft core biopsy was performed within 24 hours of initiation of anti-rejection therapy. GFL was defined as the day the allograft was presumed lost (the day the patient started dialysis, the day of nephrectomy or the day of irreversible graft loss demonstrated by imaging techniques.)
Time Frame	6 months
Safety Issue	Yes

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.
Per Protocol (PP) population.

Reporting Groups

	Description
Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Measured Values

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	**Standard Mycophenolate Sodium (Myfortic) Dosing Regimen**
Number of Participants Analyzed [units: participants]	**129**	**139**
Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death [units: number of participants]	**26**	**35**

No statistical analysis provided for Number of Patients With Treatment Failure 6-months Post Transplant Measured by the Combined Incidence of Biopsy Proven Acute Rejection, Graft Loss, and Death

3. Secondary: Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death [Time Frame: 21 and 84 days]

Measure Type	Secondary
Measure Title	Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death
Measure Description	The overall treatment differences of the number of participants with at least one occurrence of the composite event BPAR, GFL or death at study days 21 and 84 post-transplantation. BPAR was defined as a biopsy graded IA, IB, IIA, IIB or III using Banff 2000 classification. A graft core biopsy was performed within 24 hours of initiation of anti-rejection therapy. GFL was defined as the day the allograft was presumed lost (the day the patient started dialysis, the day of nephrectomy or the day of irreversible graft loss demonstrated by imaging techniques.)
Time Frame	21 and 84 days
Safety Issue	Yes

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.

Reporting Groups

	Description
Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Measured Values

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	**Standard Mycophenolate Sodium (Myfortic) Dosing Regimen**
Number of Participants Analyzed [units: participants]	**155**	**158**
Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death [units: number of participants]		
Day 21	**20**	**21**
Day 84	**33**	**34**

No statistical analysis provided for Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death

4. Secondary: Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death [Time Frame: 21 and 84 days]

Measure Type	Secondary
Measure Title	Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death
Measure Description	The overall treatment differences of the number of participants with at least one occurrence of the composite event BPAR, GFL or death at study days 21 and 84 post-transplantation. BPAR was defined as a biopsy graded IA, IB, IIA, IIB or III using Banff 2000 classification. A graft core biopsy was performed within 24 hours of initiation of anti-rejection therapy. GFL was defined as the day the allograft was presumed lost (the day the patient started dialysis, the day of nephrectomy or the day of irreversible graft loss demonstrated by imaging techniques.)
Time Frame	21 and 84 days
Safety Issue	Yes

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.
Per Protocol (PP) population.

Reporting Groups

	Description
Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was

	reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Measured Values

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	Standard Mycophenolate Sodium (Myfortic) Dosing Regimen
Number of Participants Analyzed [units: participants]	**129**	**139**
Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death [units: number of participants]		
Day 21	**14**	**20**
Day 84	**26**	**33**

No statistical analysis provided for Comparison of Overall Treatment Failure at Days 21 and 84 Post-transplantation Assessed by Biopsy Proven Acute Rejection (BPAR), GFL, and Death

5. Secondary: Renal Function Assessed by Glomerular Filtration Rate (GFR)at Each Visit [Time Frame: at 21 days, 84 days and 180 days]

Measure Type	Secondary
Measure Title	Renal Function Assessed by Glomerular Filtration Rate (GFR)at Each Visit
Measure Description	The Modification of Diet in Renal Disease (MDRD) formula was used to calculate the GFR. Serum creatinine levels, age, sex and race were used to estimate the GFR levels in mL/min/1.73m^2.
Time Frame	at 21 days, 84 days and 180 days
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.

Reporting Groups

	Description
Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Measured Values

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	Standard Mycophenolate Sodium (Myfortic) Dosing Regimen
Number of Participants Analyzed [units: participants]	**155**	**158**
Renal Function Assessed by Glomerular Filtration		

Rate (GFR)at Each Visit [units: (mL/min/1.73m^2)] Mean (Standard Deviation)		
At 21 days	**47.3 (20.05)**	**46.8 (21.00)**
At 84 days	**52.1 (19.80)**	**51.8 (20.21)**
At 180 days	**53.5 (21.05)**	**51.3 (25.14)**

No statistical analysis provided for Renal Function Assessed by Glomerular Filtration Rate (GFR)at Each Visit

6. Secondary: Renal Function Assessed by Serum Creatinine at Each Visits [Time Frame: at 21 days, 84 days and 180 days]

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 (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Serious Adverse Events

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	**Standard Mycophenolate Sodium (Myfortic) Dosing Regimen**
Total, serious adverse events		
# participants affected / at risk	**74/150 (49.33%)**	**68/154 (44.16%)**
Blood and lymphatic system disorders		
Leukopenia † 1		
# participants affected / at risk	**4/150 (2.67%)**	**0/154 (0.00%)**
Neutropenia † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Thrombocytopenia † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Thrombotic microangiopathy † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Thrombotic thrombocytopenic purpura † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Cardiac disorders		
Angina unstable † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Arrhythmia † 1		

# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Atrial fibrillation † 1		
# participants affected / at risk	3/150 (2.00%)	0/154 (0.00%)
Cardiac arrest † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Cardiac hypertrophy † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Coronary artery disease † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Myocardial ischaemia † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Ear and labyrinth disorders		
Hearing impaired † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	3/150 (2.00%)	1/154 (0.65%)
Colonic pseudo-obstruction † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Diarrhoea † 1		
# participants affected / at risk	1/150 (0.67%)	3/154 (1.95%)
Duodenal ulcer haemorrhage † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Gastritis erosive † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Ileus † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Intestinal obstruction † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
Lower gastrointestinal haemorrhage † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Nausea † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
Oesophageal ulcer † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Oesophagitis † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Peritonitis † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Retroperitoneal haematoma † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Vomiting † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
General disorders		

Chest discomfort † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Pyrexia † 1		
# participants affected / at risk	**1/150 (0.67%)**	**1/154 (0.65%)**
Immune system disorders		
Kidney transplant rejection † 1		
# participants affected / at risk	**1/150 (0.67%)**	**7/154 (4.55%)**
Transplant rejection † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Infections and infestations		
BK virus infection † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Cystitis escherichia † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Cytomegalovirus infection † 1		
# participants affected / at risk	**10/150 (6.67%)**	**16/154 (10.39%)**
Cytomegalovirus syndrome † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Gastroenteritis † 1		
# participants affected / at risk	**2/150 (1.33%)**	**1/154 (0.65%)**
Haematoma infection † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Herpes zoster † 1		
# participants affected / at risk	**1/150 (0.67%)**	**2/154 (1.30%)**
Human polyomavirus infection † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Incision site abscess † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Incision site infection † 1		
# participants affected / at risk	**0/150 (0.00%)**	**2/154 (1.30%)**
Infected lymphocele † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Lower respiratory tract infection † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Parotitis † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Pneumonia † 1		
# participants affected / at risk	**0/150 (0.00%)**	**2/154 (1.30%)**
Postoperative wound infection † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Pyelonephritis † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Renal cyst infection † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**

Sepsis † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Septic shock † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Staphylococcal bacteraemia † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Tuberculosis † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**1/150 (0.67%)**	**1/154 (0.65%)**
Urinary tract infection † 1		
# participants affected / at risk	**9/150 (6.00%)**	**11/154 (7.14%)**
Urinary tract infection enterococcal † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Urosepsis † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Viral infection † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Wound infection † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Wound infection staphylococcal † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Injury, poisoning and procedural complications		
Complications of transplanted kidney † 1		
# participants affected / at risk	**6/150 (4.00%)**	**1/154 (0.65%)**
Femur fracture † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Foreign body trauma † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Incisional hernia † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Perirenal haematoma † 1		
# participants affected / at risk	**2/150 (1.33%)**	**1/154 (0.65%)**
Post procedural haematoma † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Post procedural haematuria † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Post procedural haemorrhage † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Post procedural urine leak † 1		
# participants affected / at risk	**0/150 (0.00%)**	**2/154 (1.30%)**
Renal graft loss † 1		
# participants affected / at risk	**2/150 (1.33%)**	**4/154 (2.60%)**
Seroma † 1		

# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Shunt thrombosis † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Therapeutic agent toxicity † 1		
# participants affected / at risk	2/150 (1.33%)	0/154 (0.00%)
Wound complication † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Wound decomposition † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Wound dehiscence † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
Wrist fracture † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	5/150 (3.33%)	5/154 (3.25%)
Blood glucose increased † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Cytomegalovirus test † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Cytomegalovirus test positive † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Urine output decreased † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	2/150 (1.33%)	1/154 (0.65%)
Diabetes mellitus † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
Diabetic foot † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Diabetic ketoacidosis † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Hypercalcaemia † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Hyperglycaemia † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Hyperkalaemia † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Hypervolaemia † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Hyponatraemia † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Musculoskeletal and connective tissue disorders		

Rhabdomyolysis † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Kaposi's sarcoma † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Nervous system disorders		
Cerebrovascular accident † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Haemorrhage intracranial † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Hemiparesis † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Migraine † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Reversible posterior leukoencephalopathy syndrome † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Stupor † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Syncope † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Renal and urinary disorders		
Dysuria † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Extravasation of urine † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Haematuria † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Haemorrhage urinary tract † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Hydronephrosis † 1		
# participants affected / at risk	**2/150 (1.33%)**	**2/154 (1.30%)**
Obstructive uropathy † 1		
# participants affected / at risk	**1/150 (0.67%)**	**0/154 (0.00%)**
Renal artery stenosis † 1		
# participants affected / at risk	**1/150 (0.67%)**	**1/154 (0.65%)**
Renal failure † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Renal failure acute † 1		
# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Renal impairment † 1		
# participants affected / at risk	**2/150 (1.33%)**	**1/154 (0.65%)**
Renal tubular necrosis † 1		

# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Renal vein thrombosis † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
Ureteric obstruction † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
Ureteric stenosis † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Urinary fistula † 1		
# participants affected / at risk	0/150 (0.00%)	2/154 (1.30%)
Urinary retention † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Urinary tract obstruction † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Urinoma † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Scrotal oedema † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † 1		
# participants affected / at risk	1/150 (0.67%)	1/154 (0.65%)
Pulmonary congestion † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Tracheal stenosis † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Skin and subcutaneous tissue disorders		
Skin ulcer † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Vascular disorders		
Aortic aneurysm rupture † 1		
# participants affected / at risk	0/150 (0.00%)	1/154 (0.65%)
Arteriosclerosis † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Deep vein thrombosis † 1		
# participants affected / at risk	2/150 (1.33%)	0/154 (0.00%)
Hypertensive crisis † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Iliac artery stenosis † 1		
# participants affected / at risk	1/150 (0.67%)	0/154 (0.00%)
Lymphocele † 1		
# participants affected / at risk	1/150 (0.67%)	6/154 (3.90%)
Lymphorrhoea † 1		

# participants affected / at risk	**0/150 (0.00%)**	**1/154 (0.65%)**
Orthostatic hypotension † 1		
# participants affected / at risk	**2/150 (1.33%)**	**0/154 (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 (Myfortic) Dosing Regimen	In patients randomized to the intensified Myfortic dosing regimen, the initial dose was 2-fold of the labeled dose (i.e. 2880 mg/day). The dosage was reduced to standard level in two steps,i.e. reduction to 2160 mg/day after 2 weeks of treatment and to 1440 mg/day after 6 weeks of treatment.
Standard Mycophenolate Sodium (Myfortic) Dosing Regimen	In patients randomized to the standard Myfortic dosing regimen, the initial dose of 1440mg/day had to be maintained throughout the whole study.

Other Adverse Events

	Intensified Mycophenolate Sodium (Myfortic) Dosing Regimen	Standard Mycophenolate Sodium (Myfortic) Dosing Regimen
Total, other (not including serious) adverse events		
# participants affected / at risk	**143/150 (95.33%)**	**145/154 (94.16%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**39/150 (26.00%)**	**37/154 (24.03%)**
Leukopenia † 1		
# participants affected / at risk	**10/150 (6.67%)**	**11/154 (7.14%)**
Cardiac disorders		
Tachycardia † 1		
# participants affected / at risk	**5/150 (3.33%)**	**10/154 (6.49%)**
Gastrointestinal disorders		
Abdominal discomfort † 1		
# participants affected / at risk	**8/150 (5.33%)**	**2/154 (1.30%)**
Abdominal distension † 1		
# participants affected / at risk	**9/150 (6.00%)**	**12/154 (7.79%)**
Abdominal pain † 1		
# participants affected / at risk	**12/150 (8.00%)**	**14/154 (9.09%)**

Abdominal pain upper † 1		
# participants affected / at risk	8/150 (5.33%)	15/154 (9.74%)
Constipation † 1		
# participants affected / at risk	58/150 (38.67%)	51/154 (33.12%)
Diarrhoea † 1		
# participants affected / at risk	40/150 (26.67%)	27/154 (17.53%)
Dyspepsia † 1		
# participants affected / at risk	10/150 (6.67%)	7/154 (4.55%)
Nausea † 1		
# participants affected / at risk	43/150 (28.67%)	38/154 (24.68%)
Vomiting † 1		
# participants affected / at risk	29/150 (19.33%)	41/154 (26.62%)
General disorders		
Fatigue † 1		
# participants affected / at risk	8/150 (5.33%)	3/154 (1.95%)
Oedema † 1		
# participants affected / at risk	5/150 (3.33%)	12/154 (7.79%)
Oedema peripheral † 1		
# participants affected / at risk	42/150 (28.00%)	46/154 (29.87%)
Pain † 1		
# participants affected / at risk	7/150 (4.67%)	8/154 (5.19%)
Pyrexia † 1		
# participants affected / at risk	18/150 (12.00%)	13/154 (8.44%)
Immune system disorders		
Kidney transplant rejection † 1		
# participants affected / at risk	4/150 (2.67%)	8/154 (5.19%)
Infections and infestations		
Upper respiratory tract infection † 1		
# participants affected / at risk	15/150 (10.00%)	11/154 (7.14%)
Urinary tract infection † 1		
# participants affected / at risk	46/150 (30.67%)	38/154 (24.68%)
Injury, poisoning and procedural complications		
Complications of transplanted kidney † 1		
# participants affected / at risk	11/150 (7.33%)	14/154 (9.09%)
Incision site pain † 1		
# participants affected / at risk	16/150 (10.67%)	17/154 (11.04%)
Procedural pain † 1		
# participants affected / at risk	36/150 (24.00%)	32/154 (20.78%)
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	14/150 (9.33%)	20/154 (12.99%)
Cytomegalovirus test positive † 1		

# participants affected / at risk	9/150 (6.00%)	4/154 (2.60%)
Urine output decreased † 1		
# participants affected / at risk	7/150 (4.67%)	8/154 (5.19%)
Weight increased † 1		
# participants affected / at risk	1/150 (0.67%)	8/154 (5.19%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	8/150 (5.33%)	4/154 (2.60%)
Diabetes mellitus † 1		
# participants affected / at risk	12/150 (8.00%)	12/154 (7.79%)
Dyslipidaemia † 1		
# participants affected / at risk	8/150 (5.33%)	10/154 (6.49%)
Fluid overload † 1		
# participants affected / at risk	5/150 (3.33%)	9/154 (5.84%)
Hypercholesterolaemia † 1		
# participants affected / at risk	10/150 (6.67%)	12/154 (7.79%)
Hyperglycaemia † 1		
# participants affected / at risk	14/150 (9.33%)	19/154 (12.34%)
Hyperkalaemia † 1		
# participants affected / at risk	25/150 (16.67%)	24/154 (15.58%)
Hyperlipidaemia † 1		
# participants affected / at risk	14/150 (9.33%)	15/154 (9.74%)
Hypocalcaemia † 1		
# participants affected / at risk	12/150 (8.00%)	27/154 (17.53%)
Hypokalaemia † 1		
# participants affected / at risk	20/150 (13.33%)	11/154 (7.14%)
Hypomagnesaemia † 1		
# participants affected / at risk	22/150 (14.67%)	12/154 (7.79%)
Hypophosphataemia † 1		
# participants affected / at risk	17/150 (11.33%)	15/154 (9.74%)
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	8/150 (5.33%)	14/154 (9.09%)
Muscle spasms † 1		
# participants affected / at risk	3/150 (2.00%)	8/154 (5.19%)
Pain in extremity † 1		
# participants affected / at risk	5/150 (3.33%)	11/154 (7.14%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	9/150 (6.00%)	7/154 (4.55%)
Headache † 1		
# participants affected / at risk	19/150 (12.67%)	16/154 (10.39%)
Paraesthesia † 1		

# participants affected / at risk	6/150 (4.00%)	11/154 (7.14%)
Tremor † 1		
# participants affected / at risk	19/150 (12.67%)	20/154 (12.99%)
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	8/150 (5.33%)	12/154 (7.79%)
Insomnia † 1		
# participants affected / at risk	21/150 (14.00%)	23/154 (14.94%)
Renal and urinary disorders		
Bladder spasm † 1		
# participants affected / at risk	9/150 (6.00%)	8/154 (5.19%)
Dysuria † 1		
# participants affected / at risk	17/150 (11.33%)	13/154 (8.44%)
Haematuria † 1		
# participants affected / at risk	15/150 (10.00%)	8/154 (5.19%)
Renal tubular necrosis † 1		
# participants affected / at risk	9/150 (6.00%)	7/154 (4.55%)
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	10/150 (6.67%)	8/154 (5.19%)
Dyspnoea † 1		
# participants affected / at risk	9/150 (6.00%)	13/154 (8.44%)
Skin and subcutaneous tissue disorders		
Acne † 1		
# participants affected / at risk	9/150 (6.00%)	9/154 (5.84%)
Hirsutism † 1		
# participants affected / at risk	8/150 (5.33%)	6/154 (3.90%)
Hypertrichosis † 1		
# participants affected / at risk	3/150 (2.00%)	8/154 (5.19%)
Pruritus † 1		
# participants affected / at risk	3/150 (2.00%)	9/154 (5.84%)
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	51/150 (34.00%)	45/154 (29.22%)
Hypotension † 1		
# participants affected / at risk	11/150 (7.33%)	10/154 (6.49%)

† 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
ClinicalTrials.gov Identifier:	NCT00419926 History of Changes
Other Study ID Numbers:	**CERL080A2419**
Study First Received:	January 8, 2007
Results First Received:	December 14, 2010
Last Updated:	February 25, 2011
Health Authority:	Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment