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Trial record **1 of 1** for: CRAD001A2418

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Efficacy and Safety of Everolimus With Enteric-Coated Mycophenolate Sodium (EC-MPS) in a Cyclosporine Microemulsion-free Regimen Compared to Standard Therapy in de Novo Renal Transplant Patients

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00154310

First received: September 8, 2005
Last updated: October 21, 2013
Last verified: October 2013
History of Changes

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Results First Received: January 11, 2011

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
Interventions:	Drug: Everolimus Drug: Cyclosporine Drug: Enteric-coated mycophenolate sodium Drug: Corticosteroids

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
This study was an open-label, randomized, parallel-group, multi-center study with two treatment groups, cyclosporine continuation and cyclosporine withdrawal starting from Month 4.5 post-transplant. Study started in June 2005 and ended in September 2008.

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
Everolimus + Mycophenolate Sodium	Everolimus tablets orally twice a day to maintain a level of 6- 10 ng/mL and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5 mg prednisolone or equivalent and had to be continued throughout the first year. Cyclosporine withdrawal started from Month 4.5 post-transplant.
Cyclosporine + Mycophenolate Sodium	Cyclosporine tablets orally twice a day to achieve protocol specific target levels and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids

	were added to the immunosuppressive regimen with a minimum dose of 5mg prednisolone or equivalent and had to be continued throughout the first year.

Participant Flow: Overall Study

	Everolimus + Mycophenolate Sodium	Cyclosporine + Mycophenolate Sodium
STARTED	155 [1]	145
COMPLETED	118	117
NOT COMPLETED	37	28
Adverse Event	19	9
Lack of Efficacy	5	4
Protocol Violation	4	2
Withdrawal by Subject	9	3
Lost to Follow-up	0	8
Administrative problems	0	1
Death	0	1

[1] "Started" indicates enrolled participants. Randomized participants for two arms are 154 and 146.

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
Everolimus + Mycophenolate Sodium	Everolimus tablets orally twice a day to maintain a level of 6- 10 ng/mL and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5 mg prednisolone or equivalent and had to be continued throughout the first year. Cyclosporine withdrawal started from Month 4.5 post-transplant.
Cyclosporine + Mycophenolate Sodium	Cyclosporine tablets orally twice a day to achieve protocol specific target levels and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5mg prednisolone or equivalent and had to be continued throughout the first year.
Total	Total of all reporting groups

Baseline Measures

	Everolimus + Mycophenolate Sodium	Cyclosporine + Mycophenolate Sodium	Total
Number of Participants [units: participants]	155	145	300
Age [units: Years] Mean (Standard Deviation)	46.9 (11.67)	46.7 (11.85)	46.8 (11.73)
Gender [units: participants]			
Female	53	59	112

Male	**102**	**86**	**188**

Outcome Measures

Hide All Outcome Measures

1. Primary: Renal Function (Nankivell Formula) at Month 12 Post Transplantation. [Time Frame: at Month 12 post transplantation]

Measure Type	Primary
Measure Title	Renal Function (Nankivell Formula) at Month 12 Post Transplantation.
Measure Description	Renal function at the end of the trial assessed as mean absolute values of the glomerular filtration rate (GFR) calculated by Nankivell formula 12 months after renal transplantation. The Nankivell formula: GFR = 6.7 / Scr + BW / 4 – Surea / 2-100 / (height)^2 + C ; where Scr is the serum creatinine concentration expressed in mmol/L, BW the body weight in kg, Surea the serum urea in mmol/L, height in m, and the constant C is 35 for male and 25 for female patients. Estimated GFR is expressed in mL/min per 1.73m^2.
Time Frame	at Month 12 post transplantation
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 (randomized patients); Last Observation Carried Forward (LOCF). One patient in

Reporting Groups

	Description
Everolimus + Mycophenolate Sodium	Everolimus tablets orally twice a day to maintain a level of 6- 10 ng/mL and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5 mg prednisolone or equivalent and had to be continued throughout the first year. Cyclosporine withdrawal started from Month 4.5 post-transplant.
Cyclosporine + Mycophenolate Sodium	Cyclosporine tablets orally twice a day to achieve protocol specific target levels and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5mg prednisolone or equivalent and had to be continued throughout the first year.

Measured Values

	Everolimus + Mycophenolate Sodium	**Cyclosporine + Mycophenolate Sodium**
Number of Participants Analyzed [units: participants]	**154**	**145**
Renal Function (Nankivell Formula) at Month 12 Post Transplantation. [units: mL/min /1.73m^2] Mean (Standard Deviation)	**71.84 (18.53)**	**61.24 (16.65)**

No statistical analysis provided for Renal Function (Nankivell Formula) at Month 12 Post Transplantation.

2. Secondary: Number of Participants With Occurrence of Biopsy Proven Acute Rejection (BPAR), Graft Loss or Death [Time Frame: Up to Month 12]

Measure Type	Secondary

Measure Title	Number of Participants With Occurrence of Biopsy Proven Acute Rejection (BPAR), Graft Loss or Death
Measure Description	The number of participants with occurrence of biopsy proven acute rejection (BPAR), graft loss, or death up to Month 12 during the randomized treatment period. BPAR was defined as a biopsy graded IA, IB, IIA, IIB or III according to Banff 97 classification. A graft core biopsy was performed prior to 24 hours following initiation of graft rejection therapy. The allograft is presumed to be lost on the day the patient starts dialysis and was not able to subsequently be removed from dialysis. If the patient underwent a graft nephrectomy, then the day of nephrectomy was the day of graft loss.
Time Frame	Up to Month 12
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 (Randomized Patients)

Reporting Groups

	Description
Everolimus + Mycophenolate Sodium	Everolimus tablets orally twice a day to maintain a level of 6- 10 ng/mL and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5 mg prednisolone or equivalent and had to be continued throughout the first year. Cyclosporine withdrawal started from Month 4.5 post-transplant.
Cyclosporine + Mycophenolate Sodium	Cyclosporine tablets orally twice a day to achieve protocol specific target levels and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5mg prednisolone or equivalent and had to be continued throughout the first year.

Measured Values

	Everolimus + Mycophenolate Sodium	**Cyclosporine + Mycophenolate Sodium**
Number of Participants Analyzed [units: participants]	**154**	**146**
Number of Participants With Occurrence of Biopsy Proven Acute Rejection (BPAR), Graft Loss or Death [units: Participants]		
BPAR: Yes	**15**	**5**
BPAR: No	**139**	**141**
Graft Loss: Yes	**0**	**0**
Graft Loss: No	**154**	**146**
Death: Yes	**0**	**1**
Death: No	**154**	**145**

No statistical analysis provided for Number of Participants With Occurrence of Biopsy Proven Acute Rejection (BPAR), Graft Loss or Death

3. Secondary: Number of Participants With Occurrence of Treatment Failures [Time Frame: up to or at Month 12]

Measure Type	Secondary
Measure Title	Number of Participants With Occurrence of Treatment Failures
Measure Description	Treatment failures defined as a composite endpoint of biopsy proven acute rejection, graft loss, death, loss to follow up and discontinuations due to lack of efficacy or toxicity, or conversion to another regimen (at least one condition

	must be present).
Time Frame	up to or at Month 12
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 (Randomized Patients).

Reporting Groups

	Description
Everolimus + Mycophenolate Sodium	Everolimus tablets orally twice a day to maintain a level of 6- 10 ng/mL and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5 mg prednisolone or equivalent and had to be continued throughout the first year. Cyclosporine withdrawal started from Month 4.5 post-transplant.
Cyclosporine + Mycophenolate Sodium	Cyclosporine tablets orally twice a day to achieve protocol specific target levels and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5mg prednisolone or equivalent and had to be continued throughout the first year.

Measured Values

	Everolimus + Mycophenolate Sodium	**Cyclosporine + Mycophenolate Sodium**
Number of Participants Analyzed [units: participants]	**154**	**146**
Number of Participants With Occurrence of Treatment Failures [units: Participants]		
Treatment failure: Yes	**29**	**23**
Treatment failure: No	**125**	**123**

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

4. Secondary: Changes in Cardiovascular Risk From Month 4.5 to Final Assessment at Month 12 [Time Frame: Month 4.5 and Month 12]

Measure Type	Secondary
Measure Title	Changes in Cardiovascular Risk From Month 4.5 to Final Assessment at Month 12
Measure Description	An updated 1991 Framingham coronary prediction algorithm was used to estimate the total risk of developing coronary heart diseases (CHD) over the course of 10 years. Risk was calculated separately for male and females. To calculate risk, points were assigned for each of the following risk factors: age, levels of LDL cholesterol, HDL cholesterol, blood pressure, cigarette smoking, and diabetes mellitus. The sum of the individual risk factor points gives a total point score, which ranges from -5 to 18 for men and -16 to 24 for women. Higher points indicate a higher risk for CHD.
Time Frame	Month 4.5 and Month 12
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.

Safety Population for whom data was available at Month 4.5 and end of treatment.

Reporting Groups

	Description
Everolimus + Mycophenolate Sodium	Everolimus tablets orally twice a day to maintain a level of 6- 10 ng/mL and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5 mg prednisolone or equivalent and had to be continued throughout the first year. Cyclosporine withdrawal started from Month 4.5 post-transplant.
Cyclosporine + Mycophenolate Sodium	Cyclosporine tablets orally twice a day to achieve protocol specific target levels and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5mg prednisolone or equivalent and had to be continued throughout the first year.

Measured Values

	Everolimus + Mycophenolate Sodium	Cyclosporine + Mycophenolate Sodium
Number of Participants Analyzed [units: participants]	**155**	**145**
Changes in Cardiovascular Risk From Month 4.5 to Final Assessment at Month 12 [units: Points] Mean (Standard Deviation)		
Male (n= 55, 37)	**0.5 (1.87)**	**0.1 (1.86)**
Female (n= 22, 35)	**0.0 (2.01)**	**0.8 (2.70)**
Total Population (n= 77, 72)	**0.4 (1.91)**	**0.4 (2.32)**

No statistical analysis provided for Changes in Cardiovascular Risk From Month 4.5 to Final Assessment at Month 12

5. Secondary: Number of Participants Who Experienced an Adverse Event or Serious Adverse Event [Time Frame: Aes from end of core study period (month 12) to end of follow-up period (month 60)]

Measure Type	Secondary
Measure Title	Number of Participants Who Experienced an Adverse Event or Serious Adverse Event
Measure Description	Additional information about the number of participants who experienced Adverse Events (greater than 5%) or Serious Adverse Events can be found in the Adverse Event section.
Time Frame	Aes from end of core study period (month 12) to end of follow-up period (month 60)
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.
Safety Population consisted of all participants in whom transplantation was performed and who were treated with at least one dose of any immunosuppressive medication.

Reporting Groups

	Description
Everolimus + Mycophenolate Sodium	Everolimus tablets orally twice a day to maintain a level of 6- 10 ng/mL and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5 mg prednisolone or equivalent and had to be continued throughout the first year. Cyclosporine withdrawal started from

	Month 4.5 post-transplant.
Cyclosporine + Mycophenolate Sodium	Cyclosporine tablets orally twice a day to achieve protocol specific target levels and enteric-coated mycophenolate sodium orally twice a day to achieve a target dose of 1440 mg/day. Corticosteroids were added to the immunosuppressive regimen with a minimum dose of 5mg prednisolone or equivalent and had to be continued throughout the first year.

Measured Values

	Everolimus + Mycophenolate Sodium	Cyclosporine + Mycophenolate Sodium
Number of Participants Analyzed [units: participants]	**155**	**145**
Number of Participants Who Experienced an Adverse Event or Serious Adverse Event [units: Participants]		
Adverse Events	**155**	**145**
Serious Adverse Events	**95**	**86**

No statistical analysis provided for Number of Participants Who Experienced an Adverse Event or Serious Adverse Event

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Certican	Certican
Sandimmun Optoral	Sandimmun Optoral

Serious Adverse Events

	Certican	Sandimmun Optoral
Total, serious adverse events		
# participants affected / at risk	**103/155 (66.45%)**	**93/145 (64.14%)**
Blood and lymphatic system disorders		
Hypochromic anaemia † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Leukocytosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Leukopenia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Thrombocytopenia † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Cardiac disorders		
Acute coronary syndrome † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**

Arrhythmia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Atrial fibrillation † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Cardiac arrest † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Cardiac failure chronic † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Coronary artery disease † 1		
# participants affected / at risk	**1/155 (0.65%)**	**2/145 (1.38%)**
Myocardial infarction † 1		
# participants affected / at risk	**3/155 (1.94%)**	**1/145 (0.69%)**
Myopericarditis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Supraventricular tachycardia † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Ventricular tachycardia † 1		
# participants affected / at risk	**1/155 (0.65%)**	**1/145 (0.69%)**
Congenital, familial and genetic disorders		
Congenital cystic kidney disease † 1		
# participants affected / at risk	**1/155 (0.65%)**	**1/145 (0.69%)**
Pyloric stenosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Ear and labyrinth disorders		
Deafness † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Tinnitus † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Endocrine disorders		
Hyperparathyroidism † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Hyperparathyroidism secondary † 1		
# participants affected / at risk	**1/155 (0.65%)**	**1/145 (0.69%)**
Eye disorders		
Amaurosis fugax † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Colitis † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Constipation † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Diarrhoea † 1		

# participants affected / at risk	**6/155 (3.87%)**	**4/145 (2.76%)**
Enteritis † 1		
# participants affected / at risk	**2/155 (1.29%)**	**1/145 (0.69%)**
Gastric polyps † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Gastritis erosive † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Inguinal hernia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Nausea † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Periodontitis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Peritoneal fibrosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Peritoneal haemorrhage † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Peritonitis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Retroperitoneal haematoma † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Small intestinal perforation † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Subileus † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Vomiting † 1		
# participants affected / at risk	**1/155 (0.65%)**	**1/145 (0.69%)**
General disorders		
Catheter site haematoma † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Fat necrosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Generalised oedema † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Hernia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**2/145 (1.38%)**
Hernia obstructive † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Impaired healing † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Non-cardiac chest pain † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Oedema peripheral † 1		
# participants affected / at risk	**0/155 (0.00%)**	**2/145 (1.38%)**

Pyrexia † 1		
# participants affected / at risk	**5/155 (3.23%)**	**1/145 (0.69%)**
Hepatobiliary disorders		
Hydrocholecystis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Immune system disorders		
Transplant rejection † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Infections and infestations		
Aspergilloma † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Bacterial infection † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Bronchitis † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Bronchopulmonary aspergillosis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Chronic sinusitis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Cystitis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Cytomegalovirus infection † 1		
# participants affected / at risk	**6/155 (3.87%)**	**5/145 (3.45%)**
Diverticulitis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Endocarditis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Enterococcal infection † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Erysipelas † 1		
# participants affected / at risk	**0/155 (0.00%)**	**2/145 (1.38%)**
Febrile infection † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Gastroenteritis † 1		
# participants affected / at risk	**7/155 (4.52%)**	**4/145 (2.76%)**
Gastroenteritis salmonella † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Gastroenteritis viral † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Gastrointestinal infection † 1		
# participants affected / at risk	**2/155 (1.29%)**	**1/145 (0.69%)**
Herpes zoster † 1		
# participants affected / at risk	**0/155 (0.00%)**	**3/145 (2.07%)**
Human polyomavirus infection † 1		

# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Infected lymphocele † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Infection † 1		
# participants affected / at risk	2/155 (1.29%)	1/145 (0.69%)
Lung infection † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Nasopharyngitis † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Pneumocystis jiroveci pneumonia † 1		
# participants affected / at risk	3/155 (1.94%)	2/145 (1.38%)
Pneumonia † 1		
# participants affected / at risk	8/155 (5.16%)	16/145 (11.03%)
Pyelonephritis † 1		
# participants affected / at risk	4/155 (2.58%)	3/145 (2.07%)
Renal cyst infection † 1		
# participants affected / at risk	1/155 (0.65%)	1/145 (0.69%)
Respiratory tract infection † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Sepsis † 1		
# participants affected / at risk	1/155 (0.65%)	1/145 (0.69%)
Shunt infection † 1		
# participants affected / at risk	0/155 (0.00%)	2/145 (1.38%)
Sinusitis † 1		
# participants affected / at risk	2/155 (1.29%)	0/145 (0.00%)
Superinfection † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Tracheitis † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Urinary tract infection † 1		
# participants affected / at risk	18/155 (11.61%)	14/145 (9.66%)
Urosepsis † 1		
# participants affected / at risk	5/155 (3.23%)	4/145 (2.76%)
Viral upper respiratory tract infection † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Wound infection † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Injury, poisoning and procedural complications		
Abdominal wound dehiscence † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Anastomotic complication † 1		
# participants affected / at risk	2/155 (1.29%)	0/145 (0.00%)
Anastomotic haemorrhage † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)

Arteriovenous fistula thrombosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Chronic allograft nephropathy † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Complications of transplanted kidney † 1		
# participants affected / at risk	**3/155 (1.94%)**	**7/145 (4.83%)**
Fat embolism † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Femur fracture † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Foot fracture † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Incision site haematoma † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Muscle rupture † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Operative haemorrhage † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Perirenal haematoma † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Post procedural haematoma † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Post procedural haemorrhage † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Postoperative hernia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Renal haematoma † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Renal lymphocele † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Seroma † 1		
# participants affected / at risk	**3/155 (1.94%)**	**0/145 (0.00%)**
Shunt thrombosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**2/145 (1.38%)**
Spinal compression fracture † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Subcutaneous haematoma † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Transplant failure † 1		
# participants affected / at risk	**1/155 (0.65%)**	**1/145 (0.69%)**
Urethral injury † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Wound dehiscence † 1		
# participants affected / at risk	**1/155 (0.65%)**	**4/145 (2.76%)**

Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	**10/155 (6.45%)**	**15/145 (10.34%)**
Blood urea increased † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Cytomegalovirus test † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Haemoglobin decreased † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Occult blood positive † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Transaminases increased † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	**1/155 (0.65%)**	**3/145 (2.07%)**
Diabetes mellitus † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Fluid retention † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Hypercalcaemia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Hyperglycaemia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Hyperkalaemia † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Hyponatraemia † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Tetany † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Musculoskeletal and connective tissue disorders		
Arthritis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Arthropathy † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Haemarthrosis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Myopathy steroid † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Osteonecrosis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**1/145 (0.69%)**
Pain in extremity † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Rhabdomyolysis † 1		

# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Synovial cyst † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma † 1		
# participants affected / at risk	3/155 (1.94%)	2/145 (1.38%)
Bladder cancer † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Bowen's disease † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Fibrous histiocytoma † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Kaposi's sarcoma † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Neoplasm skin † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Parathyroid tumour benign † 1		
# participants affected / at risk	0/155 (0.00%)	2/145 (1.38%)
Prostate cancer † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Renal cell carcinoma † 1		
# participants affected / at risk	2/155 (1.29%)	0/145 (0.00%)
Squamous cell carcinoma † 1		
# participants affected / at risk	2/155 (1.29%)	0/145 (0.00%)
Thyroid neoplasm † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Uterine leiomyoma † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Nervous system disorders		
Aphasia † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Cerebrovascular accident † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Convulsion † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	1/155 (0.65%)	1/145 (0.69%)
Dysphoria † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Psychiatric decompensation † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Renal and urinary disorders		
Focal segmental glomerulosclerosis † 1		

# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Hydronephrosis † 1		
# participants affected / at risk	3/155 (1.94%)	0/145 (0.00%)
IgA nephropathy † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Nephritis autoimmune † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Nephropathy † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Nephropathy toxic † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Nephrosclerosis † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Proteinuria † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Renal artery stenosis † 1		
# participants affected / at risk	3/155 (1.94%)	1/145 (0.69%)
Renal disorder † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Renal failure † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Renal failure acute † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Renal haemorrhage † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Renal impairment † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Renal tubular disorder † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Ureteral necrosis † 1		
# participants affected / at risk	1/155 (0.65%)	1/145 (0.69%)
Ureteric stenosis † 1		
# participants affected / at risk	3/155 (1.94%)	3/145 (2.07%)
Urethral discharge † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Urethral perforation † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Urethral stenosis † 1		
# participants affected / at risk	1/155 (0.65%)	1/145 (0.69%)
Urinary incontinence † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Urinary retention † 1		
# participants affected / at risk	2/155 (1.29%)	2/145 (1.38%)
Urinary tract disorder † 1		

# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Urinary tract obstruction † 1		
# participants affected / at risk	2/155 (1.29%)	0/145 (0.00%)
Urinoma † 1		
# participants affected / at risk	2/155 (1.29%)	0/145 (0.00%)
Vesicoureteric reflux † 1		
# participants affected / at risk	1/155 (0.65%)	1/145 (0.69%)
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Cervical dysplasia † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Ovarian cyst † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Pelvic congestion † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Postmenopausal haemorrhage † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Scrotal oedema † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Vaginal haemorrhage † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Bronchitis chronic † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Dyspnoea † 1		
# participants affected / at risk	0/155 (0.00%)	2/145 (1.38%)
Interstitial lung disease † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Lung infiltration † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Pulmonary embolism † 1		
# participants affected / at risk	3/155 (1.94%)	1/145 (0.69%)
Respiratory arrest † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)
Respiratory failure † 1		
# participants affected / at risk	1/155 (0.65%)	1/145 (0.69%)
Stridor † 1		
# participants affected / at risk	0/155 (0.00%)	1/145 (0.69%)
Skin and subcutaneous tissue disorders		
Erythema nodosum † 1		
# participants affected / at risk	1/155 (0.65%)	0/145 (0.00%)

Pyoderma gangrenosum † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Rash † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Skin ulcer † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Surgical and medical procedures		
Kidney anastomosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Vascular disorders		
Arterial restenosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Deep vein thrombosis † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Haematoma † 1		
# participants affected / at risk	**3/155 (1.94%)**	**2/145 (1.38%)**
Haemorrhage † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Hypertension † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Hypertensive crisis † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Hypotension † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Lymphocele † 1		
# participants affected / at risk	**9/155 (5.81%)**	**14/145 (9.66%)**
Peripheral artery aneurysm † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Shock haemorrhagic † 1		
# participants affected / at risk	**2/155 (1.29%)**	**0/145 (0.00%)**
Thrombosis † 1		
# participants affected / at risk	**0/155 (0.00%)**	**1/145 (0.69%)**
Venous thrombosis † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (0.00%)**
Venous thrombosis limb † 1		
# participants affected / at risk	**1/155 (0.65%)**	**0/145 (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
Certican	Certican
Sandimmun Optoral	Sandimmun Optoral

Other Adverse Events

	Certican	Sandimmun Optoral
Total, other (not including serious) adverse events		
# participants affected / at risk	**155/155 (100.00%)**	**145/145 (100.00%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**43/155 (27.74%)**	**35/145 (24.14%)**
Leukocytosis † 1		
# participants affected / at risk	**17/155 (10.97%)**	**22/145 (15.17%)**
Leukopenia † 1		
# participants affected / at risk	**24/155 (15.48%)**	**24/145 (16.55%)**
Thrombocytopenia † 1		
# participants affected / at risk	**18/155 (11.61%)**	**5/145 (3.45%)**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**7/155 (4.52%)**	**9/145 (6.21%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**20/155 (12.90%)**	**14/145 (9.66%)**
Abdominal pain upper † 1		
# participants affected / at risk	**12/155 (7.74%)**	**12/145 (8.28%)**
Aphthous stomatitis † 1		
# participants affected / at risk	**22/155 (14.19%)**	**3/145 (2.07%)**
Constipation † 1		
# participants affected / at risk	**82/155 (52.90%)**	**72/145 (49.66%)**
Diarrhoea † 1		
# participants affected / at risk	**60/155 (38.71%)**	**42/145 (28.97%)**
Dyspepsia † 1		
# participants affected / at risk	**15/155 (9.68%)**	**11/145 (7.59%)**
Flatulence † 1		
# participants affected / at risk	**25/155 (16.13%)**	**20/145 (13.79%)**
Nausea † 1		
# participants affected / at risk	**64/155 (41.29%)**	**59/145 (40.69%)**
Vomiting † 1		
# participants affected / at risk	**38/155 (24.52%)**	**32/145 (22.07%)**

General disorders		
Asthenia † 1		
# participants affected / at risk	**2/155 (1.29%)**	**9/145 (6.21%)**
Fatigue † 1		
# participants affected / at risk	**7/155 (4.52%)**	**10/145 (6.90%)**
Impaired healing † 1		
# participants affected / at risk	**8/155 (5.16%)**	**5/145 (3.45%)**
Oedema † 1		
# participants affected / at risk	**44/155 (28.39%)**	**34/145 (23.45%)**
Oedema peripheral † 1		
# participants affected / at risk	**38/155 (24.52%)**	**32/145 (22.07%)**
Pain † 1		
# participants affected / at risk	**30/155 (19.35%)**	**26/145 (17.93%)**
Pyrexia † 1		
# participants affected / at risk	**24/155 (15.48%)**	**22/145 (15.17%)**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**16/155 (10.32%)**	**7/145 (4.83%)**
Cytomegalovirus infection † 1		
# participants affected / at risk	**26/155 (16.77%)**	**24/145 (16.55%)**
Gastroenteritis † 1		
# participants affected / at risk	**15/155 (9.68%)**	**17/145 (11.72%)**
Gastrointestinal infection † 1		
# participants affected / at risk	**10/155 (6.45%)**	**7/145 (4.83%)**
Herpes zoster † 1		
# participants affected / at risk	**8/155 (5.16%)**	**10/145 (6.90%)**
Human polyomavirus infection † 1		
# participants affected / at risk	**8/155 (5.16%)**	**3/145 (2.07%)**
Infection † 1		
# participants affected / at risk	**9/155 (5.81%)**	**9/145 (6.21%)**
Nasopharyngitis † 1		
# participants affected / at risk	**49/155 (31.61%)**	**44/145 (30.34%)**
Oral herpes † 1		
# participants affected / at risk	**11/155 (7.10%)**	**1/145 (0.69%)**
Pneumonia † 1		
# participants affected / at risk	**16/155 (10.32%)**	**9/145 (6.21%)**
Respiratory tract infection † 1		
# participants affected / at risk	**12/155 (7.74%)**	**12/145 (8.28%)**
Rhinitis † 1		
# participants affected / at risk	**12/155 (7.74%)**	**8/145 (5.52%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**12/155 (7.74%)**	**7/145 (4.83%)**
Urinary tract infection † 1		
# participants affected / at risk	**90/155 (58.06%)**	**83/145 (57.24%)**

Wound infection † 1		
# participants affected / at risk	**4/155 (2.58%)**	**11/145 (7.59%)**
Injury, poisoning and procedural complications		
Complications of transplanted kidney † 1		
# participants affected / at risk	**21/155 (13.55%)**	**24/145 (16.55%)**
Procedural pain † 1		
# participants affected / at risk	**50/155 (32.26%)**	**48/145 (33.10%)**
Wound complication † 1		
# participants affected / at risk	**51/155 (32.90%)**	**46/145 (31.72%)**
Wound dehiscence † 1		
# participants affected / at risk	**6/155 (3.87%)**	**8/145 (5.52%)**
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	**51/155 (32.90%)**	**49/145 (33.79%)**
C-reactive protein increased † 1		
# participants affected / at risk	**7/155 (4.52%)**	**8/145 (5.52%)**
Weight increased † 1		
# participants affected / at risk	**8/155 (5.16%)**	**14/145 (9.66%)**
Metabolism and nutrition disorders		
Diabetes mellitus † 1		
# participants affected / at risk	**19/155 (12.26%)**	**12/145 (8.28%)**
Fluid retention † 1		
# participants affected / at risk	**6/155 (3.87%)**	**12/145 (8.28%)**
Hypercalcaemia † 1		
# participants affected / at risk	**15/155 (9.68%)**	**25/145 (17.24%)**
Hypercholesterolaemia † 1		
# participants affected / at risk	**45/155 (29.03%)**	**41/145 (28.28%)**
Hyperglycaemia † 1		
# participants affected / at risk	**24/155 (15.48%)**	**16/145 (11.03%)**
Hyperkalaemia † 1		
# participants affected / at risk	**18/155 (11.61%)**	**21/145 (14.48%)**
Hyperlipidaemia † 1		
# participants affected / at risk	**23/155 (14.84%)**	**16/145 (11.03%)**
Hyperphosphataemia † 1		
# participants affected / at risk	**11/155 (7.10%)**	**12/145 (8.28%)**
Hypertriglyceridaemia † 1		
# participants affected / at risk	**11/155 (7.10%)**	**5/145 (3.45%)**
Hyperuricaemia † 1		
# participants affected / at risk	**10/155 (6.45%)**	**20/145 (13.79%)**
Hypocalcaemia † 1		
# participants affected / at risk	**23/155 (14.84%)**	**27/145 (18.62%)**
Hypokalaemia † 1		
# participants affected / at risk	**45/155 (29.03%)**	**36/145 (24.83%)**

Hypomagnesaemia † 1		
# participants affected / at risk	**8/155 (5.16%)**	**13/145 (8.97%)**
Hyponatraemia † 1		
# participants affected / at risk	**6/155 (3.87%)**	**10/145 (6.90%)**
Hypophosphataemia † 1		
# participants affected / at risk	**47/155 (30.32%)**	**43/145 (29.66%)**
Hypoproteinaemia † 1		
# participants affected / at risk	**8/155 (5.16%)**	**11/145 (7.59%)**
Iron deficiency † 1		
# participants affected / at risk	**3/155 (1.94%)**	**8/145 (5.52%)**
Metabolic acidosis † 1		
# participants affected / at risk	**15/155 (9.68%)**	**10/145 (6.90%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**16/155 (10.32%)**	**12/145 (8.28%)**
Back pain † 1		
# participants affected / at risk	**26/155 (16.77%)**	**15/145 (10.34%)**
Muscle spasms † 1		
# participants affected / at risk	**9/155 (5.81%)**	**10/145 (6.90%)**
Myalgia † 1		
# participants affected / at risk	**10/155 (6.45%)**	**4/145 (2.76%)**
Pain in extremity † 1		
# participants affected / at risk	**14/155 (9.03%)**	**5/145 (3.45%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**25/155 (16.13%)**	**21/145 (14.48%)**
Tremor † 1		
# participants affected / at risk	**10/155 (6.45%)**	**9/145 (6.21%)**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**35/155 (22.58%)**	**32/145 (22.07%)**
Sleep disorder † 1		
# participants affected / at risk	**21/155 (13.55%)**	**20/145 (13.79%)**
Renal and urinary disorders		
Bladder pain † 1		
# participants affected / at risk	**8/155 (5.16%)**	**11/145 (7.59%)**
Dysuria † 1		
# participants affected / at risk	**7/155 (4.52%)**	**9/145 (6.21%)**
Haematuria † 1		
# participants affected / at risk	**28/155 (18.06%)**	**31/145 (21.38%)**
Leukocyturia † 1		
# participants affected / at risk	**22/155 (14.19%)**	**18/145 (12.41%)**
Polyuria † 1		
# participants affected / at risk	**10/155 (6.45%)**	**16/145 (11.03%)**

Proteinuria † 1		
# participants affected / at risk	**25/155 (16.13%)**	**25/145 (17.24%)**
Urinary retention † 1		
# participants affected / at risk	**11/155 (7.10%)**	**4/145 (2.76%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**26/155 (16.77%)**	**29/145 (20.00%)**
Dyspnoea † 1		
# participants affected / at risk	**19/155 (12.26%)**	**17/145 (11.72%)**
Skin and subcutaneous tissue disorders		
Acne † 1		
# participants affected / at risk	**14/155 (9.03%)**	**11/145 (7.59%)**
Hypertrichosis † 1		
# participants affected / at risk	**5/155 (3.23%)**	**8/145 (5.52%)**
Rash † 1		
# participants affected / at risk	**8/155 (5.16%)**	**4/145 (2.76%)**
Vascular disorders		
Haematoma † 1		
# participants affected / at risk	**8/155 (5.16%)**	**8/145 (5.52%)**
Hypertension † 1		
# participants affected / at risk	**17/155 (10.97%)**	**22/145 (15.17%)**
Hypotension † 1		
# participants affected / at risk	**22/155 (14.19%)**	**32/145 (22.07%)**
Lymphocele † 1		
# participants affected / at risk	**17/155 (10.97%)**	**23/145 (15.86%)**

† 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:

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No publications provided by Novartis

Publications automatically indexed to this study:

Budde K, Becker T, Arns W, Sommerer C, Reinke P, Eisenberger U, Kramer S, Fischer W, Gschaidmeier H, Pietruck F; ZEUS Study Investigators. Everolimus-based, calcineurin-inhibitor-free regimen in recipients of de-novo kidney transplants: an open-label, randomised, controlled trial. Lancet. 2011 Mar 5;377(9768):837-47. doi: 10.1016/S0140-6736(10)62318-5. Epub 2011 Feb 19. Erratum in: Lancet. 2012 Dec 8;380(9858):1994. Lancet. 2011 Jun 11;377(9782):2006. Wüthrich, Rudolf P [added].

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