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Trial record **1 of 1** for: CRAD001A2419

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Everolimus in a Cyclosporine Microemulsion-free Regimen Compared to a Low-dose Cyclosporine Microemulsion Regimen, in de Novo Kidney Transplant Patients (CERTES02)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00154284

First received: September 8, 2005
Last updated: March 28, 2011
Last verified: March 2011
History of Changes

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Results First Received: January 4, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Organ Transplantation, Renal Transplantation
Interventions:	Drug: Everolimus (Certican) Drug: Cyclosporine (Neoral) Drug: Steroid Drug: Basiliximab (Simulect)

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
Subjects were recruited from Spain from July 2005 to July 2008. As per protocol amendment, data were analyzed together with data from study CRAD001A2423 (NCT00154284) and CRAD001A2423 (NCT00170807).

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 (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Participant Flow: Overall Study

	Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal
STARTED	**59** [1]	**55**
Intent to Treat (ITT) Population	**57**	**53**
COMPLETED	**52** [2]	**42**
NOT COMPLETED	**7**	**13**
Adverse Event	**6**	**9**
Abnormal laboratory value(s)	**0**	**1**
Lack of Efficacy	**1**	**2**
Protocol Violation	**0**	**1**
Withdrawal by Subject	**0**	**0**
Administrative problems	**0**	**0**
Graft loss	**0**	**0**

[1] "Started" indicates Safety Population (randomized patients and treated after randomization.)
[2] "Completed" means patients completed on study medication.All patients of both arms completed study.

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 (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided

	doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Total	Total of all reporting groups

Baseline Measures

	Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Total
Number of Participants [units: participants]	**59**	**55**	**114**
Age [units: years] Mean (Standard Deviation)	**45.7 (11.62)**	**41.5 (12.27)**	**43.6 (12.07)**
Gender [units: participants]			
Female	**18**	**20**	**38**
Male	**41**	**35**	**76**

Outcome Measures

Hide All Outcome Measures

1. Primary: Renal Function Measured by Calculated Glomerular Filtration Rate (GFR Calculated According to the Nankivell Formula) [Time Frame: At Month 3 and Month 12]

Measure Type	Primary
Measure Title	Renal Function Measured by Calculated Glomerular Filtration Rate (GFR Calculated According to the Nankivell Formula)
Measure Description	Nankivell's formula for calculated GFR is shown below: GFR [mL/min] = 6.7/C + W/4 – UREA/2 – 100/H2+ 35 (25 for females). Where W is body weight at specific visit [kg], H is height at specific visit [m], C is the serum concentration of creatinine [mmol/L], and UREA is the serum concentration of urea [mmol/L]. UREA was calculated from blood urea nitrogen (BUN) lab data by: UREA = 2.1441*BUN. If a GFR value from Nankivell formula was less than 10 [mL/min], then the value was assigned as 10 [mL/min].
Time Frame	At Month 3 and 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.

Reporting Groups

	Description
Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided

	doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Measured Values

	Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal
Number of Participants Analyzed [units: participants]	**57**	**53**
Renal Function Measured by Calculated Glomerular Filtration Rate (GFR Calculated According to the Nankivell Formula) [units: mL/min per 1.73 m^2] Mean (Standard Deviation)		
GFR at 3 months (Pre-randomization)	**68.5 (19.92)**	**69.2 (18.40)**
GFR at 12 months	**63.6 (14.61)**	**68.3 (15.13)**

No statistical analysis provided for Renal Function Measured by Calculated Glomerular Filtration Rate (GFR Calculated According to the Nankivell Formula)

2. Secondary: Number of Participants With Biopsy-proven Acute Rejection (BPAR) Episodes, Graft Loss, Death or Loss to Follow-up [Time Frame: Month 12]

Measure Type	Secondary
Measure Title	Number of Participants With Biopsy-proven Acute Rejection (BPAR) Episodes, Graft Loss, Death or Loss to Follow-up
Measure Description	Renal biopsies were collected for all cases of suspected acute rejection. For these cases, regardless of initiation of anti-rejection treatment, a graft core biopsy had been performed within 48 hours. These biopsies were listed on the Kidney Allograft Biopsy eCRF and the results used for patient management for BPAR. Graft loss was defined as the allograft was presumed to be lost on the day the patient started dialysis and was not able to subsequently be removed from dialysis as well as re-transplant. BPAR, graft loss, death, or loss to follow-up was analyzed by means of frequency tables.
Time Frame	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.

Reporting Groups

	Description

Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Measured Values

	Everolimus (Certican) With Cyclosporine (Neoral) Continuation	**Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal**
Number of Participants Analyzed [units: participants]	**57**	**53**
Number of Participants With Biopsy-proven Acute Rejection (BPAR) Episodes, Graft Loss, Death or Loss to Follow-up [units: Participants]		
Biopsy-proven Acute Rejection (BPAR)	**10**	**10**
Graft Loss	**0**	**0**
Death	**0**	**0**
Loss to Follow-up	**0**	**0**

No statistical analysis provided for Number of Participants With Biopsy-proven Acute Rejection (BPAR) Episodes, Graft Loss, Death or Loss to Follow-up

3. Secondary: Serum Creatinine at Month 6 and 12 [Time Frame: 6 month and 12 months]

Measure Type	Secondary
Measure Title	Serum Creatinine at Month 6 and 12
Measure Description	serum creatinine summarized by mean and standard deviation
Time Frame	6 month and 12 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.
Intention to treat (ITT) population.

Reporting Groups

	Description

Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Measured Values

	Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	**Everolimus (Certican) With Cyclosporine (Neoral) Continuation**
Number of Participants Analyzed [units: participants]	**53**	**57**
Serum Creatinine at Month 6 and 12 [units: µmol/L] Mean (Standard Deviation)		
6 Month	**120.1 (31.22)**	**139.1 (47.03)**
12 Month	**123.0 (40.28)**	**135.6 (40.61)**

No statistical analysis provided for Serum Creatinine at Month 6 and 12

4. Secondary: Calculated Creatinine Clearance at 6 Month and 12 Month [Time Frame: 6 month and 12 months]

Measure Type	Secondary
Measure Title	Calculated Creatinine Clearance at 6 Month and 12 Month
Measure Description	Creatinine clearance calculated by Cockcroft-Gault formula and summarized by mean, and standard deviation. Cockcroft-Gault formula to calculate Creatinine Clearance (CrCl[mL/min]) is shown below: CrCl[mL/min] = (140 – A) * W / (72 * C) * R. Where A is age at sample date [years], W is body weight at specific visit [kg], C is the serum concentration of creatinine [mg/dL], R = 1 if the patient is male and = 0.85 if female.
Time Frame	6 month and 12 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.
Intention to treat (ITT) population.

Reporting Groups

	Description

Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Measured Values

	Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Everolimus (Certican) With Cyclosporine (Neoral) Continuation
Number of Participants Analyzed [units: participants]	**53**	**57**
Calculated Creatinine Clearance at 6 Month and 12 Month [units: mL/min] Mean (Standard Deviation)		
6 Month	**72.9 (19.34)**	**63.6 (19.65)**
12 Month	**72.3 (20.50)**	**65.6 (19.24)**

No statistical analysis provided for Calculated Creatinine Clearance at 6 Month and 12 Month

5. Secondary: Safety Based on Adverse Event (AE) Reporting [Time Frame: 12 month]

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

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-

	transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Serious Adverse Events

	Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Everolimus (Certican) With Cyclosporine (Neoral) Continuation
Total, serious adverse events		
# participants affected / at risk	**16/55 (29.09%)**	**14/59 (23.73%)**
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	**0/55 (0.00%)**	**1/59 (1.69%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**1/55 (1.82%)**	**1/59 (1.69%)**
Stomatitis † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Vomiting † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
General disorders		
Pyrexia † 1		
# participants affected / at risk	**1/55 (1.82%)**	**1/59 (1.69%)**
Immune system disorders		
Transplant rejection † 1		
# participants affected / at risk	**0/55 (0.00%)**	**2/59 (3.39%)**
Infections and infestations		
Abdominal wall infection † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Anal abscess † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Appendiceal abscess † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Appendicitis † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Bronchitis † 1		
# participants affected / at risk	**0/55 (0.00%)**	**1/59 (1.69%)**
Enterocolitis infectious † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Febrile infection † 1		
# participants affected / at risk	**0/55 (0.00%)**	**1/59 (1.69%)**
Gastroenteritis † 1		
# participants affected / at risk	**2/55 (3.64%)**	**2/59 (3.39%)**

Pneumonia † 1		
# participants affected / at risk	**1/55 (1.82%)**	**1/59 (1.69%)**
Pneumonia bacterial † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Renal cyst infection † 1		
# participants affected / at risk	**0/55 (0.00%)**	**1/59 (1.69%)**
Sepsis † 1		
# participants affected / at risk	**1/55 (1.82%)**	**2/59 (3.39%)**
Soft tissue infection † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Urinary tract infection † 1		
# participants affected / at risk	**0/55 (0.00%)**	**3/59 (5.08%)**
Injury, poisoning and procedural complications		
Complications of transplanted kidney † 1		
# participants affected / at risk	**1/55 (1.82%)**	**1/59 (1.69%)**
Foot fracture † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Renal lymphocele † 1		
# participants affected / at risk	**0/55 (0.00%)**	**1/59 (1.69%)**
Wound dehiscence † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Metabolism and nutrition disorders		
Diabetes mellitus † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Hypovolaemia † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Renal and urinary disorders		
Calculus urinary † 1		
# participants affected / at risk	**0/55 (0.00%)**	**1/59 (1.69%)**
Haematuria † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Hydronephrosis † 1		
# participants affected / at risk	**0/55 (0.00%)**	**1/59 (1.69%)**
Renal failure acute † 1		
# participants affected / at risk	**3/55 (5.45%)**	**0/59 (0.00%)**
Renal impairment † 1		
# participants affected / at risk	**0/55 (0.00%)**	**2/59 (3.39%)**
Reproductive system and breast disorders		
Uterine haemorrhage † 1		

# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Vascular disorders		
Haemorrhage † 1		
# participants affected / at risk	**1/55 (1.82%)**	**0/59 (0.00%)**
Lymphocele † 1		
# participants affected / at risk	**1/55 (1.82%)**	**2/59 (3.39%)**

† 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
Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. Therefore, patients were randomized to cyclosporine withdrawal over a period of 1 month (±1 week) in study A2419 (NCT00154284) and over 3 months (±1 week) in study A2423 (NCT00170807). After randomization, final target trough range for everolimus was 8 - 12 ng/mL. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.
Everolimus (Certican) With Cyclosporine (Neoral) Continuation	Patients were treated with everolimus and cyclosporine for 3 months post-transplantation. Everolimus (Certican) was administered orally, in two divided doses (b.i.d), and at the same time as Cyclosporine (Neoral). Everolimus (Certican) dose was adjusted in order to maintain a trough level between 3 and 8 ng/mL until randomization. After randomization the target trough range remained at 3 - 8 ng/mL in the cyclosporine (Neoral) continuation groups for a period of 9 months. Each patient was administered i.v. prednisone (or equivalent) pre- or intra-operatively according to center practice.

Other Adverse Events

	Everolimus (Certican) With Cyclosporine (Neoral) Withdrawal	**Everolimus (Certican) With Cyclosporine (Neoral) Continuation**
Total, other (not including serious) adverse events		
# participants affected / at risk	**38/55 (69.09%)**	**35/59 (59.32%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**5/55 (9.09%)**	**8/59 (13.56%)**
Polycythaemia † 1		

# participants affected / at risk	**3/55 (5.45%)**	**1/59 (1.69%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**3/55 (5.45%)**	**5/59 (8.47%)**
General disorders		
Oedema † 1		
# participants affected / at risk	**6/55 (10.91%)**	**4/59 (6.78%)**
Oedema peripheral † 1		
# participants affected / at risk	**6/55 (10.91%)**	**4/59 (6.78%)**
Pyrexia † 1		
# participants affected / at risk	**4/55 (7.27%)**	**5/59 (8.47%)**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**1/55 (1.82%)**	**3/59 (5.08%)**
Gastroenteritis † 1		
# participants affected / at risk	**3/55 (5.45%)**	**0/59 (0.00%)**
Nasopharyngitis † 1		
# participants affected / at risk	**7/55 (12.73%)**	**1/59 (1.69%)**
Urinary tract infection † 1		
# participants affected / at risk	**5/55 (9.09%)**	**9/59 (15.25%)**
Metabolism and nutrition disorders		
Dyslipidaemia † 1		
# participants affected / at risk	**4/55 (7.27%)**	**2/59 (3.39%)**
Hypercholesterolaemia † 1		
# participants affected / at risk	**2/55 (3.64%)**	**6/59 (10.17%)**
Hypertriglyceridaemia † 1		
# participants affected / at risk	**2/55 (3.64%)**	**3/59 (5.08%)**
Musculoskeletal and connective tissue disorders		
Myalgia † 1		
# participants affected / at risk	**0/55 (0.00%)**	**3/59 (5.08%)**
Renal and urinary disorders		
Proteinuria † 1		
# participants affected / at risk	**4/55 (7.27%)**	**1/59 (1.69%)**
Renal impairment † 1		
# participants affected / at risk	**4/55 (7.27%)**	**4/59 (6.78%)**
Skin and subcutaneous tissue disorders		
Acne † 1		
# participants affected / at risk	**4/55 (7.27%)**	**0/59 (0.00%)**

† 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
This is a combined analysis using 81 patients randomized and treated in CRAD001A2419 with 33 randomized and treated in CRAD001A2423. This approach is reflected in the protocol amendments for each study, and the one clinical study report for both.

More Information

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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

Publications of Results:

Grinyo JM, Paul J, Novoa P, et al. (2010). Better renal function in renal-transplant recipients treated with everolimus plus cyclosporine elimination compared with cyclosporine minimisation, Am J Transplant; 10(Suppl 4): 503: Abstract 1636.

Responsible Party:	novartis
ClinicalTrials.gov Identifier:	NCT00154284 History of Changes
Obsolete Identifiers:	NCT00170807
Other Study ID Numbers:	**CRAD001A2419** CRAD001A2423 (Other Identifier: Novartis Pharmaceuticals)
Study First Received:	September 8, 2005
Results First Received:	January 4, 2011
Last Updated:	March 28, 2011
Health Authority:	Spain: Agencia Española de Medicamentos y Productos Sanitarios