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Trial record **1 of 1** for: CRAD001ASE01

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Evaluation of Early Conversion to Everolimus From Cyclosporine in de Novo Renal Transplant Recipients

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00634920

First received: March 6, 2008
Last updated: August 12, 2014
Last verified: August 2014
History of Changes

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Results First Received: May 6, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Renal Function
Interventions:	Drug: everolimus Drug: cyclosporine A Drug: Enteric Coated Mycophenolate Sodium (EC-MPS) Drug: corticosteroids Drug: Basiliximab

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
The study consisted of 2 periods, period 1: TX to Week 7 ± 7 days post-TX and period 2: Week 7 ± 7 days post-TX to Month 36. 341 patients were enrolled in this study. 204 randomized to receive study treatment: 104 in the everolimus group, 100 in the control group. 2 patients in everolimus group did not receive at least one dose of study treatment.

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen

	consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.
Pre-Randomized Patients	All patients received induction therapy with 20 mg basiliximab on Day 0 prior to reperfusion and 20 mg at Day 4 post-TX (transplatation), and commenced on an immunosuppressive regimen consisting of: CsA (based on trough levels C0-h 100-250 ng/mL or C2-h 900 1300 ng/mL, according to local method), EC MPS (target dose 1440 mg/day, minimum dose 1080 mg/day at the time of randomization), Corticosteroids (a minimum dose of 10 mg prednisolone or equivalent was given at time of randomization).

Participant Flow for 2 periods

Period 1: Period 1 - Pre-Randomization

	Everolimus (CNI-free)	Control (CsA)	Pre-Randomized Patients
STARTED	0	0	341 [1]
COMPLETED	0	0	204 [2]
NOT COMPLETED	0	0	137
Adverse Event	0	0	36
Wound healing problems	0	0	16
Rejections	0	0	55
Withdrawal by Subject	0	0	21
Non-Compliance	0	0	3
Other issues	0	0	6

[1] Total number of Enrolled patients
[2] Total number of patients who became randomized

Period 2: Period 2 - Post-Randomization

	Everolimus (CNI-free)	Control (CsA)	Pre-Randomized Patients
STARTED	104 [1]	100	0 [2]
Full Analysis Set (FAS)	92	90	0
COMPLETED	43	68	0
NOT COMPLETED	61	32	0
Adverse Event	37	9	0
Rejection	11	5	0
Death	2	5	0
consent withdrawal, non compliance	9	13	0
Patients did not receive study drug	2	0	0

[1] 2 patients randomized in this group did not receive at least one dose of study drug.
[2] This group included patients who had renal TX but did not qualify for randomization at Visit 2.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.
Not Randomized Patients	This group included patients in whom a renal TX was performed but who did not qualify for randomization at Visit 2. This group was to be described with respect to treatment, reason for not randomized and outcome variables calculated or measured GFR, whichever was feasible, BPAR, graft loss or death at 12 months (no outcome variables were collected for this population
Total	Total of all reporting groups

Baseline Measures

	Everolimus (CNI-free)	Control (CsA)	Not Randomized Patients	Total
Number of Participants [units: participants]	**104**	**100**	**137**	**341**
Age [units: Years] Mean (Standard Deviation)	**55.0 (10.9)**	**53.3 (12.3)**	**56.3 (12.5)**	**55.0 (12.0)**
Gender [units: Participants]				
Female	**34**	**26**	**43**	**103**
Male	**70**	**74**	**94**	**238**
Race/Ethnicity, Customized [units: Participants]				
Caucasian	**101**	**100**	**136**	**337**
Black	**1**	**0**	**0**	**1**
Oriental	**2**	**0**	**1**	**3**

Outcome Measures

Hide All Outcome Measures

1. Primary: Measured Glomerular Filtration Rate [Time Frame: Month 12]

Measure Type	Primary
Measure Title	Measured Glomerular Filtration Rate
Measure Description	To compare the efficacy between treatment regimens by assessing the difference in renal function evaluated by mean measured glomerular filtration rate (mGFR) 12 months after renal transplantation (TX). The mGFR was measured using Iohexol or Cr-EDTA clearance according to local practice.
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Measured Glomerular Filtration Rate [units: mL/min/1.73m^2] Mean (Standard Deviation)	**51.5 (14.4)**	**47.8 (15.4)**

No statistical analysis provided for Measured Glomerular Filtration Rate

2. Secondary: Measured Glomerular Filtration Rate [Time Frame: Month 36]

Measure Type	Secondary
Measure Title	Measured Glomerular Filtration Rate
Measure Description	Progression of renal function measured by mean mGFR at 36 months after renal TX. The mGFR was measured using Iohexol or Cr-EDTA clearance according to local practice.
Time Frame	Month 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR). Patients who did not provide mGFR assessment at M36 visit were excluded from the analysis.

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.

Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	Control (CsA)
Number of Participants Analyzed [units: participants]	**87**	**90**
Measured Glomerular Filtration Rate [units: mL/min/1.73m^2] Mean (Standard Deviation)	**48.2 (14.7)**	**46.1 (17.0)**

No statistical analysis provided for Measured Glomerular Filtration Rate

3. Secondary: Calculated Glomerular Filtration Rate [Time Frame: Months 12, 36]

Measure Type	Secondary
Measure Title	Calculated Glomerular Filtration Rate
Measure Description	The GFR was calculated according to the Modification of Diet in Renal Disease Study Group (MDRD) method, the Cockcroft-Gault method, and the Nankivell formula. cGFR was calculated from blood samples collected at predefined time points.
Time Frame	Months 12, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	Control (CsA)
Number of Participants Analyzed [units: participants]	**92**	**90**
Calculated Glomerular Filtration Rate [units: mL/min/1.73m^2] Mean (Standard Deviation)		

MDRD M12	**65.0 (19.9)**	**60.1 (19.7)**
MDRD M36	**59.4 (20.1)**	**57.4 (20.2)**
Cockcroft-Gault M12	**45.4 (14.6)**	**45.6 (15.4)**
Cockcroft-Gault M36	**43.1 (16.1)**	**42.1 (13.1)**
Nankivel M12	**66.3 (19.2)**	**61.8 (20.5)**
Nankivel M36	**61.8 (20.9)**	**58.9 (20.0)**

No statistical analysis provided for Calculated Glomerular Filtration Rate

4. Secondary: Progression of Measured Glomerular Filtration Rate [Time Frame: Week 7, Week 52, Month 36]

Measure Type	Secondary
Measure Title	Progression of Measured Glomerular Filtration Rate
Measure Description	Change in renal progression measured by mean mGFR from week 7 to Month 36
Time Frame	Week 7, Week 52, Month 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Progression of Measured Glomerular Filtration Rate [units: mL/min/1.73m^2] Mean (Standard Deviation)		
Week 7	**46.3 (13.0)**	**47.8 (15.0)**
Week 52	**51.5 (14.4)**	**47.8 (15.4)**
Change from week 7 to Week 52	**5.6 (11.5)**	**0.0 (12.9)**
Month 36	**48.2 (14.7)**	**46.1 (17.0)**
Change from week 7 to Month 36	**1.3 (14.0)**	**-1.7 (15.4)**

No statistical analysis provided for Progression of Measured Glomerular Filtration Rate

5. Secondary: Percentage of Participants Who Developed CAN (Chronic Allograft Nephropathy) [Time Frame: Month 12, Month 36]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Developed CAN (Chronic Allograft Nephropathy)
Measure Description	Assessed by protocol biopsies findings (Banff 1997 lesion scores and morphometry of the interstitial space)
Time Frame	Month 12, Month 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Percentage of Participants Who Developed CAN (Chronic Allograft Nephropathy) [units: Percentage of participants]		
Month 12	**1.0**	**1.0**
Month 36	**59.0**	**64.0**

No statistical analysis provided for Percentage of Participants Who Developed CAN (Chronic Allograft Nephropathy)

6. Secondary: Percentage of Participants With Biopsy Proven Acute Rejection (BPAR) [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Percentage of Participants With Biopsy Proven Acute Rejection (BPAR)
Measure Description	A BPAR was defined as a biopsy graded IA, IB, IIA, IIB, or III (Banff 97 classification). Biopsy graded IA: Significant interstitial infiltration (> 25% of parenchyma) and foci of moderate tubulitis (> 4 mononuclear cells/tubular cross section or group of 10 tubular cells). Biopsy grade IB: Significant interstitial infiltration (> 25% of parenchyma) and foci of

	severe tubulitis (> 10 mononuclear cells/tubular cross section or group of 10 tubular cells). Biopsy grade IIA: Mild to moderate intimal arteritis. Biopsy graded IIB: Severe intimal arteritis comprising > 25% of the lumenal area.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Percentage of Participants With Biopsy Proven Acute Rejection (BPAR) [units: Percentage of participants]		
Month 12: IA	**19.6**	**4.4**
Month 12: IB	**10.9**	**0.0**
Month 12: IIA	**2.2**	**2.2**
Month 12: IIB	**2.2**	**1.1**
Month 24: IA	**5.4**	**4.4**
Month 24: IB	**1.1**	**3.3**
Month 36: IA	**2.2**	**1.1**
Month 36: IB	**1.1**	**0.0**

No statistical analysis provided for Percentage of Participants With Biopsy Proven Acute Rejection (BPAR)

7. Secondary: Percentage of Participants With Graft Loss or Death [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Percentage of Participants With Graft Loss or Death
Measure Description	The allograft was presumed to be lost on the day the patient started dialysis and was not able to subsequently be removed from dialysis. If the patient underwent a graft nephrectomy, the day of nephrectomy was the day of graft loss. Graft loss was considered an SAE (serious adverse event).
Time Frame	Months 12, 24, 36

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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Percentage of Participants With Graft Loss or Death [units: Percentage of participants]		
Month 12: Event First Year	**0.0**	**0.0**
Month 12: No Event First Year	**100.0**	**100.0**
Month 24: Event Second Year	**1.1**	**1.1**
Month 24: No Event Second Year	**98.9**	**98.9**
Month 36: Event Third Year	**0.0**	**2.2**
Month 36: No Event Third Year	**100.0**	**97.8**

No statistical analysis provided for Percentage of Participants With Graft Loss or Death

8. Secondary: Time to Treatment Failure [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Time to Treatment Failure
Measure Description	Treatment failure was defined as graft loss or death.Time to treatment failure is shown as mean time to treatment failure.
Time Frame	Months 12, 24, 36
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.

The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	Control (CsA)
Number of Participants Analyzed [units: participants]	**92**	**90**
Time to Treatment Failure [units: Days] Mean (Standard Error)	**972.7 (7.76)**	**959.5 (7.76)**

No statistical analysis provided for Time to Treatment Failure

9. Secondary: Percentage of Participants With Treatment Failures [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Percentage of Participants With Treatment Failures
Measure Description	Treatment failure was defined as graft loss or death.
Time Frame	Months 12, 24, 36
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.

The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	Control (CsA)
Number of Participants Analyzed [units: participants]	**92**	**90**
Percentage of Participants With Treatment Failures [units: Percentage of participants]		
Month 12: No Failure	**100.0**	**100.0**
Month 12: Failure	**0.0**	**0.0**
Month 24: No Failure	**98.8**	**98.8**
Month 24: Failure	**1.2**	**1.2**
Month 36: No Failure	**98.8**	**96.7**
Month 36: Failure	**1.2**	**3.3**

No statistical analysis provided for Percentage of Participants With Treatment Failures

10. Secondary: Time to First Malignancy [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Time to First Malignancy
Measure Description	This is the time to first diagnosed malignancy. Malignancies (skin- or solid cancer) were listed whether they reoccurred in situ, were metastatic or de novo. This is shown as mean time.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	Control (CsA)
Number of Participants Analyzed [units: participants]	**92**	**90**
Time to First Malignancy		

[units: Months] Mean (Standard Error)	**35.5 (0.63)**	**35.1 (0.55)**

No statistical analysis provided for Time to First Malignancy

11. Secondary: Lipid Profile for Apolipoprotein [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Lipid Profile for Apolipoprotein
Measure Description	Blood lipid levels of patients in both groups for Apolipoprotein (Apo) A1 and B.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Lipid Profile for Apolipoprotein [units: g/L] Mean (Standard Deviation)		
Month 12: Apolipoprotein A1	**1.59 (0.31)**	**1.46 (0.26)**
Month 24: Apolipoprotein A1	**1.55 (0.29)**	**1.36 (0.06)**
Month 36: Apolipoprotein A1	**1.70 (0.39)**	**1.56 (0.33)**
Month 12: Apolipoprotein B	**0.935 (0.235)**	**0.923 (0.258)**
Month 24: Apolipoprotein B (	**1.178 (0.225)**	**1.058 (0.263)**
Month 36: Apolipoprotein B	**0.984 (0.211)**	**0.934 (0.206)**

No statistical analysis provided for Lipid Profile for Apolipoprotein

12. Secondary: Lipid Profile for HDL-C, LDL-C,Total Cholesterol, and Triglycerides [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Lipid Profile for HDL-C, LDL-C,Total Cholesterol, and Triglycerides
Measure Description	Blood lipid levels of patients in both groups: HDL-C, LDL-C,Total cholesterol, and triglycerides.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Lipid Profile for HDL-C, LDL-C,Total Cholesterol, and Triglycerides [units: mmol/L] Mean (Standard Deviation)		
Month 12: HDL Cholesterol	**1.486 (0.446)**	**1.419 (0.409)**
Month 24: HDL Cholesterol	**1.477 (0.437)**	**1.409 (0.411)**
Month 36: HDL Cholesterol	**1.495 (0.440)**	**1.529 (0.518)**
Month 12: LDL Cholesterol	**3.569 (1.390)**	**3.130 (0.962)**
Month 24: LDL Cholesterol	**3.381 (1.139)**	**2.925 (1.043)**
Month 36: LDL Cholesterol	**3.206 (0.945)**	**2.822 (0.789)**
Month 12: Total Cholesterol	**6.091 (1.650)**	**5.318 (1.067)**
Month 24: Total Cholesterol	**5.823 (1.377)**	**5.112 (1.096)**
Month 36: Total Cholesterol	**5.595 (1.396)**	**4.830 (1.166)**
Month 12: Triglycerides	**2.461 (1.620)**	**1.868 (0.932)**
Month 24: Triglycerides	**2.288 (1.400)**	**1.757 (0.958)**
Month 36: Triglycerides	**2.164 (1.256)**	**1.580 (0.853)**

No statistical analysis provided for Lipid Profile for HDL-C, LDL-C,Total Cholesterol, and Triglycerides

13. Secondary: Number of Lipid-lowering Drugs Taken [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Number of Lipid-lowering Drugs Taken
Measure Description	No text entered.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Number of Lipid-lowering Drugs Taken [units: Number of lipid-lowering drugs] Mean (Standard Deviation)		
Month 12	**0.9 (0.4)**	**0.8 (0.4)**
Month 24	**1.0 (0.4)**	**0.9 (0.4)**
Month 36	**0.9 (0.5)**	**0.8 (0.4)**

No statistical analysis provided for Number of Lipid-lowering Drugs Taken

14. Secondary: Percentage of Participants on Lipid-lowering Drugs [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Percentage of Participants on Lipid-lowering Drugs
Measure Description	No text entered.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Percentage of Participants on Lipid-lowering Drugs [units: Percentage of participants]		
Month 12	**75.0**	**60.0**
Month 24	**78.0**	**65.0**
Month 36	**73.0**	**63.0**

No statistical analysis provided for Percentage of Participants on Lipid-lowering Drugs

15. Secondary: Number of Antihypertensive Drugs Taken [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Number of Antihypertensive Drugs Taken
Measure Description	No text entered.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were

	randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	Control (CsA)
Number of Participants Analyzed [units: participants]	**92**	**90**
Number of Antihypertensive Drugs Taken [units: Number of antihypertensive dugs] Mean (Standard Deviation)		
Month 12	**2.5 (1.4)**	**2.5 (1.1)**
Month 24	**2.5 (1.3)**	**2.4 (1.1)**
Month 36	**2.0 (1.4)**	**2.2 (1.3)**

No statistical analysis provided for Number of Antihypertensive Drugs Taken

16. Secondary: Percentage of Participants on Antihypertensive Drugs [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Percentage of Participants on Antihypertensive Drugs
Measure Description	No text entered.
Time Frame	Months 12, 24, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	Control (CsA)

Number of Participants Analyzed [units: participants]	**92**	**90**
Percentage of Participants on Antihypertensive Drugs [units: Percentage of participants]		
Month 12: No antihypertensive drugs	**9.2**	**3.3**
Month 12: Has antihypertensive drugs	**90.8**	**96.7**
Month 24: No antihypertensive drugs	**4.2**	**5.3**
Month 24: Has antihypertensive drugs	**95.8**	**94.7**
Month 36: No antihypertensive drugs	**15.6**	**12.8**
Month 36: Has antihypertensive drugs	**84.4**	**87.2**

No statistical analysis provided for Percentage of Participants on Antihypertensive Drugs

17. Secondary: Proteinuria (Measured as Urine Albumin/Creatinine Ratio (mg/mmol)) [Time Frame: Months 12, 24, 36]

Measure Type	Secondary
Measure Title	Proteinuria (Measured as Urine Albumin/Creatinine Ratio (mg/mmol))
Measure Description	Proteinuria is when a large amount of protein, that should remain circulating in a person's blood, is "spilled" into their urine and eliminated from the body.
Time Frame	Months 12, 24, 36
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.
The safety population (SAF) consists of all patients in whom TX was performed and who were randomized and treated with at least one dose of randomized treatment.

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**102**	**100**
Proteinuria (Measured as Urine Albumin/Creatinine Ratio (mg/mmol)) [units: mg/mmol] Mean (Standard Deviation)		
Month 12	**17.31 (29.39)**	**11.27 (22.92)**

Month 24	**62.83 (178.62)**	**24.55 (52.07)**
Month 36	**78.78 (357.45)**	**80.73 (534.30)**

No statistical analysis provided for Proteinuria (Measured as Urine Albumin/Creatinine Ratio (mg/mmol))

18. Secondary: Percentage of Participants Who Had Donor Specific Antibodies (DSA) [Time Frame: Month 36]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Had Donor Specific Antibodies (DSA)
Measure Description	Venous blood was drawn for donor specific (DSA) measurements prior to transplantation and at the final visit (36 months). The blood sample was first screened for the presence of PRA i.e. donor specific Immunoglobulin-G antibodies against specific HLA antigens. If PRA antibodies were detected, the blood sample was tested for specific DSAs on single antigen Luminex beads (coated with single HLA class I or II molecules). In this way, the specificity of these antibodies could be determined.
Time Frame	Month 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Percentage of Participants Who Had Donor Specific Antibodies (DSA) [units: Percentage of participants]		
ND (not done)	**7.0**	**9.0**
Negative	**78.0**	**70.0**
Positive	**15.0**	**21.0**

No statistical analysis provided for Percentage of Participants Who Had Donor Specific Antibodies (DSA)

19. Secondary: Health-related Quality of Life (QoL) as Measured by EuroQoL EQ-5D [Time Frame: Before randomization, Months 12, 36]

Measure Type	Secondary
Measure Title	Health-related Quality of Life (QoL) as Measured by EuroQoL EQ-5D
Measure Description	Health-related QoL was assessed using the EQ-5D questionnaire. The EQ-5D self-report questionnaire consists of the EQ-5D descriptive system that measures health-related quality of life on 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each of which can take one of three responses. The responses record three levels of severity (no problems/moderate problems/severe problems) within a particular EQ-5D dimension. Scores are transformed to a range of 0-1, in which higher scores reflect better health status.
Time Frame	Before randomization, Months 12, 36
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.
The full analysis set (FAS) population consists of all randomized patients who received at least one dose of any immunosuppressive therapy after TX and have both baseline and Month 12 assessment of the primary efficacy variable (renal function based on mGFR).

Reporting Groups

	Description
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.

Measured Values

	Everolimus (CNI-free)	**Control (CsA)**
Number of Participants Analyzed [units: participants]	**92**	**90**
Health-related Quality of Life (QoL) as Measured by EuroQoL EQ-5D [units: scores on a scale] Mean (Standard Deviation)		
Before Randomization (Week 7)	**0.8430 (0.1539)**	**0.8693 (0.1583)**
Month 12	**0.8155 (0.1605)**	**0.8470 (0.2239)**
Month 36	**0.8285 (0.2303)**	**0.8422 (0.1941)**

No statistical analysis provided for Health-related Quality of Life (QoL) as Measured by EuroQoL EQ-5D

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.

Serious Adverse Events

	Control (CsA)	Everolimus (CNI-free)
Total, serious adverse events		
# participants affected / at risk	**65/100 (65.00%)**	**72/102 (70.59%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Febrile neutropenia † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Leukopenia † 1		
# participants affected / at risk	**3/100 (3.00%)**	**0/102 (0.00%)**
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Angina pectoris † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Atrial fibrillation † 1		
# participants affected / at risk	**1/100 (1.00%)**	**3/102 (2.94%)**
Cardiac arrest † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Cardiac failure † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Myocardial infarction † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Supraventricular tachycardia † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Ventricular fibrillation † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Congenital, familial and genetic disorders		
Polycystic liver disease † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**

Endocrine disorders		
Hyperparathyroidism † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Gastrointestinal disorders		
Abdominal hernia † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Abdominal pain † 1		
# participants affected / at risk	**2/100 (2.00%)**	**1/102 (0.98%)**
Aphthous stomatitis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Colitis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Constipation † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Diabetic gastroparesis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Diarrhoea † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Gastritis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Haematemesis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Impaired gastric emptying † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Melaena † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Vomiting † 1		
# participants affected / at risk	**0/100 (0.00%)**	**2/102 (1.96%)**
General disorders		
Chest pain † 1		
# participants affected / at risk	**2/100 (2.00%)**	**4/102 (3.92%)**
Death † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
General physical health deterioration † 1		
# participants affected / at risk	**0/100 (0.00%)**	**3/102 (2.94%)**
Metaplasia † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Pain † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Pyrexia † 1		
# participants affected / at risk	**0/100 (0.00%)**	**7/102 (6.86%)**
Hepatobiliary disorders		

Cholelithiasis † 1		
# participants affected / at risk	**2/100 (2.00%)**	**0/102 (0.00%)**
Immune system disorders		
Graft versus host disease † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Transplant rejection † 1		
# participants affected / at risk	**9/100 (9.00%)**	**4/102 (3.92%)**
Infections and infestations		
Abscess † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Acute tonsillitis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
BK virus infection † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Bronchitis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**2/102 (1.96%)**
Campylobacter infection † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Clostridium colitis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Cystitis † 1		
# participants affected / at risk	**2/100 (2.00%)**	**1/102 (0.98%)**
Cytomegalovirus gastroenteritis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Cytomegalovirus infection † 1		
# participants affected / at risk	**6/100 (6.00%)**	**4/102 (3.92%)**
Device related infection † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Epstein-Barr viraemia † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Erysipelas † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Gangrene † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Gastroenteritis † 1		
# participants affected / at risk	**3/100 (3.00%)**	**8/102 (7.84%)**
Gastroenteritis caliciviral † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Gastroenteritis norovirus † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Gastroenteritis salmonella † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Gastroenteritis viral † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**

H1N1 influenza † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Herpes simplex † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Herpes zoster † 1		
# participants affected / at risk	**0/100 (0.00%)**	**2/102 (1.96%)**
Infected lymphocele † 1		
# participants affected / at risk	**0/100 (0.00%)**	**2/102 (1.96%)**
Infection † 1		
# participants affected / at risk	**1/100 (1.00%)**	**4/102 (3.92%)**
Lung infection † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Nasopharyngitis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Pneumocystis jiroveci pneumonia † 1		
# participants affected / at risk	**0/100 (0.00%)**	**2/102 (1.96%)**
Pneumonia † 1		
# participants affected / at risk	**6/100 (6.00%)**	**15/102 (14.71%)**
Pyelonephritis † 1		
# participants affected / at risk	**5/100 (5.00%)**	**4/102 (3.92%)**
Pyelonephritis acute † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Rectal abscess † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Renal cyst infection † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Respiratory tract infection viral † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Sepsis † 1		
# participants affected / at risk	**2/100 (2.00%)**	**5/102 (4.90%)**
Subcutaneous abscess † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**0/100 (0.00%)**	**2/102 (1.96%)**
Urinary tract infection † 1		
# participants affected / at risk	**10/100 (10.00%)**	**10/102 (9.80%)**
Urosepsis † 1		
# participants affected / at risk	**3/100 (3.00%)**	**4/102 (3.92%)**
Viral infection † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Wound infection † 1		
# participants affected / at risk	**0/100 (0.00%)**	**4/102 (3.92%)**
Injury, poisoning and procedural complications		
Complications of transplant surgery † 1		

# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Femur fracture † 1		
# participants affected / at risk	1/100 (1.00%)	0/102 (0.00%)
Foot fracture † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Graft complication † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Joint dislocation † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Overdose † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Pelvic fracture † 1		
# participants affected / at risk	1/100 (1.00%)	0/102 (0.00%)
Poisoning † 1		
# participants affected / at risk	1/100 (1.00%)	0/102 (0.00%)
Post procedural haemorrhage † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Post-traumatic pain † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Postoperative fever † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Pubis fracture † 1		
# participants affected / at risk	1/100 (1.00%)	0/102 (0.00%)
Radius fracture † 1		
# participants affected / at risk	1/100 (1.00%)	1/102 (0.98%)
Rib fracture † 1		
# participants affected / at risk	1/100 (1.00%)	0/102 (0.00%)
Subdural haematoma † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Toxicity to various agents † 1		
# participants affected / at risk	2/100 (2.00%)	0/102 (0.00%)
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	4/100 (4.00%)	8/102 (7.84%)
Norovirus test positive † 1		
# participants affected / at risk	1/100 (1.00%)	0/102 (0.00%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	3/100 (3.00%)	1/102 (0.98%)
Diabetes mellitus inadequate control † 1		
# participants affected / at risk	0/100 (0.00%)	1/102 (0.98%)
Diabetic ketoacidosis † 1		
# participants affected / at risk	1/100 (1.00%)	0/102 (0.00%)
Hyperglycaemia † 1		

# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Hyperkalaemia † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Hypoglycaemia † 1		
# participants affected / at risk	**2/100 (2.00%)**	**1/102 (0.98%)**
Ketoacidosis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Neck pain † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Osteoarthritis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Osteonecrosis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Adenocarcinoma † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Basal cell carcinoma † 1		
# participants affected / at risk	**2/100 (2.00%)**	**5/102 (4.90%)**
Bowen's disease † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Breast cancer † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Chronic myeloid leukaemia † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Haemangioma † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Lung neoplasm malignant † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Non-small cell lung cancer † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Parathyroid tumour benign † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Small cell lung cancer stage unspecified † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Squamous cell carcinoma † 1		
# participants affected / at risk	**3/100 (3.00%)**	**2/102 (1.96%)**
Nervous system disorders		
Cerebral haemorrhage † 1		
# participants affected / at risk	**1/100 (1.00%)**	**2/102 (1.96%)**
Cerebral infarction † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**

Cerebrovascular accident † 1		
# participants affected / at risk	**1/100 (1.00%)**	**1/102 (0.98%)**
Cerebrovascular disorder † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Convulsion † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Diabetic neuropathy † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Encephalitis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Epilepsy † 1		
# participants affected / at risk	**1/100 (1.00%)**	**2/102 (1.96%)**
Monoparesis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Paraesthesia † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Presyncope † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Subarachnoid haemorrhage † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Syncope † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Renal and urinary disorders		
Bladder perforation † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Dysuria † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Glomerulonephritis rapidly progressive † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Haematuria † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Hydronephrosis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**3/102 (2.94%)**
Nephropathy toxic † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Nephrotic syndrome † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Renal cyst † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Renal impairment † 1		
# participants affected / at risk	**0/100 (0.00%)**	**2/102 (1.96%)**

Urethral stenosis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Urinary retention † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Breast enlargement † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Pulmonary embolism † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Surgical and medical procedures		
Knee arthroplasty † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Manual lymphatic drainage † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Nephrectomy † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Transurethral prostatectomy † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Vesicoureteral reflux surgery † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Vascular disorders		
Arterial stenosis † 1		
# participants affected / at risk	**1/100 (1.00%)**	**0/102 (0.00%)**
Deep vein thrombosis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Haematoma † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Lymphocele † 1		
# participants affected / at risk	**3/100 (3.00%)**	**4/102 (3.92%)**
Thrombosis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**
Vena cava thrombosis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**1/102 (0.98%)**

† 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
Control (CsA)	All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the control group continued on the prior immunosuppressive regimen given before randomization. Conventional treatment arm with cyclosporine (CsA), mycophenolate (Myfortic) and corticosteroids continued for the entire 36 months study period.
Everolimus (CNI-free)	This investigational drug was provided by Novartis. All patients received induction therapy with basiliximab, and commenced on an immunosuppressive regimen consisting of CsA, EC-MPS and corticosteroids before they were randomized. After randomization patients in the everolimus group (CNI-free regimen) were treated with everolimus (Certican) EC MPS and corticosteroids. Patients randomized to this arm 7 weeks after renal transplantation will do an overnight switch from cyclosporine to everolimus.

Other Adverse Events

	Control (CsA)	Everolimus (CNI-free)
Total, other (not including serious) adverse events		
# participants affected / at risk	**88/100 (88.00%)**	**93/102 (91.18%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**12/100 (12.00%)**	**24/102 (23.53%)**
Leukopenia † 1		
# participants affected / at risk	**10/100 (10.00%)**	**15/102 (14.71%)**
Gastrointestinal disorders		
Aphthous stomatitis † 1		
# participants affected / at risk	**0/100 (0.00%)**	**14/102 (13.73%)**
Diarrhoea † 1		
# participants affected / at risk	**15/100 (15.00%)**	**12/102 (11.76%)**
Gingival hyperplasia † 1		
# participants affected / at risk	**10/100 (10.00%)**	**0/102 (0.00%)**
General disorders		
Fatigue † 1		
# participants affected / at risk	**8/100 (8.00%)**	**3/102 (2.94%)**
Oedema † 1		
# participants affected / at risk	**4/100 (4.00%)**	**13/102 (12.75%)**
Oedema peripheral † 1		
# participants affected / at risk	**28/100 (28.00%)**	**32/102 (31.37%)**
Infections and infestations		
Cytomegalovirus infection † 1		
# participants affected / at risk	**8/100 (8.00%)**	**5/102 (4.90%)**
Gastroenteritis † 1		

# participants affected / at risk	6/100 (6.00%)	6/102 (5.88%)
Herpes zoster † 1		
# participants affected / at risk	7/100 (7.00%)	2/102 (1.96%)
Nasopharyngitis † 1		
# participants affected / at risk	21/100 (21.00%)	16/102 (15.69%)
Oral fungal infection † 1		
# participants affected / at risk	1/100 (1.00%)	6/102 (5.88%)
Pneumonia † 1		
# participants affected / at risk	6/100 (6.00%)	9/102 (8.82%)
Upper respiratory tract infection † 1		
# participants affected / at risk	7/100 (7.00%)	6/102 (5.88%)
Urinary tract infection † 1		
# participants affected / at risk	31/100 (31.00%)	30/102 (29.41%)
Injury, poisoning and procedural complications		
Wound † 1		
# participants affected / at risk	2/100 (2.00%)	6/102 (5.88%)
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	13/100 (13.00%)	5/102 (4.90%)
Polyomavirus test positive † 1		
# participants affected / at risk	9/100 (9.00%)	10/102 (9.80%)
Metabolism and nutrition disorders		
Gout † 1		
# participants affected / at risk	11/100 (11.00%)	1/102 (0.98%)
Hypercholesterolaemia † 1		
# participants affected / at risk	5/100 (5.00%)	11/102 (10.78%)
Hyperkalaemia † 1		
# participants affected / at risk	5/100 (5.00%)	1/102 (0.98%)
Hyperlipidaemia † 1		
# participants affected / at risk	12/100 (12.00%)	17/102 (16.67%)
Hypokalaemia † 1		
# participants affected / at risk	2/100 (2.00%)	8/102 (7.84%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	11/100 (11.00%)	6/102 (5.88%)
Myalgia † 1		
# participants affected / at risk	5/100 (5.00%)	10/102 (9.80%)
Osteoporosis † 1		
# participants affected / at risk	3/100 (3.00%)	9/102 (8.82%)
Pain in extremity † 1		
# participants affected / at risk	4/100 (4.00%)	6/102 (5.88%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	8/100 (8.00%)	1/102 (0.98%)

Headache † 1		
# participants affected / at risk	**6/100 (6.00%)**	**8/102 (7.84%)**
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	**8/100 (8.00%)**	**3/102 (2.94%)**
Renal and urinary disorders		
Proteinuria † 1		
# participants affected / at risk	**4/100 (4.00%)**	**14/102 (13.73%)**
Reproductive system and breast disorders		
Erectile dysfunction † 1		
# participants affected / at risk	**2/100 (2.00%)**	**6/102 (5.88%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**7/100 (7.00%)**	**10/102 (9.80%)**
Skin and subcutaneous tissue disorders		
Acne † 1		
# participants affected / at risk	**2/100 (2.00%)**	**14/102 (13.73%)**
Actinic keratosis † 1		
# participants affected / at risk	**5/100 (5.00%)**	**0/102 (0.00%)**
Hirsutism † 1		
# participants affected / at risk	**8/100 (8.00%)**	**1/102 (0.98%)**
Rash † 1		
# participants affected / at risk	**5/100 (5.00%)**	**10/102 (9.80%)**
Vascular disorders		
Lymphocele † 1		
# participants affected / at risk	**5/100 (5.00%)**	**3/102 (2.94%)**

† 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 or disclosure of trial results in their entirety.

Results Point of Contact:

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No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00634920 History of Changes
Other Study ID Numbers:	**CRAD001ASE01** 2007-000771-42 (EudraCT Number)
Study First Received:	March 6, 2008
Results First Received:	May 6, 2014
Last Updated:	August 12, 2014
Health Authority:	United States: Food and Drug Administration Sweden: Medical Products Agency Norway: Norwegian Medicines Agency Denmark: Danish Medicines Agency Finland: Finnish Medicines Agency