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Trial record **1 of 1** for: CRAD001ADE19

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# Study to Evaluate the Efficacy, Safety and Tolerability of Everolimus in de Novo Renal Transplant Recipients Participating in the Eurotransplant Senior Program (Senator)

**This study has been terminated.**

*(The study was terminated because the required sample size of 240-260 de novo senior renal transplant patients was not achieved within a reasonable time.)*

**Sponsor:**
Novartis Pharmaceuticals

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

**ClinicalTrials.gov Identifier:**
NCT00956293

First received: August 7, 2009
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Last verified: May 2014
History of Changes

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Results First Received: March 26, 2014

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment |
| **Condition:** | Renal Transplantation |
| **Interventions:** | Drug: Basiliximab<br>Drug: Enteric Coated Mycophenolic Acid (MPA)<br>Drug: RAD001<br>Drug: Cyclosporin A (CsA)<br>Drug: Corticosteroids |

## Participant Flow

Hide Participant Flow

### Recruitment Details

| Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations |
|---|
| The study consisted of a main period and a 54 month observation follow-up period. The main period included a pre-randomized treatment phase (6 weeks) and a randomized treatment phase (18 weeks). All randomized participants, who participated in the main period, were eligible for the follow-up period. |

### Pre-Assignment Details

| Significant events and approaches for the overall study following participant enrollment, but prior to group assignment |
|---|
| At baseline (BL) 1 (pre-randomization), eligible participants received a CNI-based regimen for 6 weeks. At BL2 (randomization), eligible participants were randomized in a 1:2 ratio to the control group or everolimus group. |

### Reporting Groups

| | Description |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |

| | |
|---|---|
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |
| **Pre-randomized Group** | Participants, who met BL1 eligibility, were enrolled into the study. |

**Participant Flow for 3 periods**

**Period 1: Main Period (Pre-randomization)**

| | Control Group | Everolimus Group | Pre-randomized Group |
|---|---|---|---|
| **STARTED** | 0 | 0 | 207 |
| **Enrolled Safety Set** | 0 | 0 | 203 |
| **COMPLETED** | 0 | 0 | 77 |
| **NOT COMPLETED** | 0 | 0 | 130 |
| **Not specified (data missing)** | 0 | 0 | 1 |
| **Death** | 0 | 0 | 1 |
| **Protocol Violation** | 0 | 0 | 1 |
| **Abnormal test procedure result** | 0 | 0 | 2 |
| **Administrative problems** | 0 | 0 | 6 |
| **Graft loss** | 0 | 0 | 7 |
| **Withdrawal by Subject** | 0 | 0 | 12 |
| **Lack of Efficacy** | 0 | 0 | 20 |
| **Adverse Event** | 0 | 0 | 36 |
| **Abnormal laboratory value** | 0 | 0 | 44 |

**Period 2: Main Period (Randomization)**

| | Control Group | Everolimus Group | Pre-randomized Group |
|---|---|---|---|
| **STARTED** | 24 | 53 | 0 |
| **Full Analysis Set** | 24 | 51 [1] | 0 |
| **Randomized Safety Set** | 24 | 51 | 0 |
| **COMPLETED** | 23 | 26 | 0 |
| **NOT COMPLETED** | 1 | 27 | 0 |
| **Abnormal laboratory value** | 0 | 2 | 0 |
| **Lack of Efficacy** | 1 | 10 | 0 |
| **Adverse Event** | 0 | 15 | 0 |

[1] Two participants, randomized to this arm, did not receive everolimus.

**Period 3: Follow-up Period**

| | Control Group | Everolimus Group | Pre-randomized Group |
|---|---|---|---|
| **STARTED** | 20 | 32 | 0 |
| **COMPLETED** | 0 | 0 | 0 |
| **NOT COMPLETED** | 20 | 32 | 0 |
| **Follow-up period was terminated.** | 20 | 32 | 0 |

## 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** |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | **Control Group** | **Everolimus Group** | **Total** |
|---|---|---|---|
| **Number of Participants [units: participants]** | **24** | **51** | **75** |
| **Age [units: Years] Mean (Standard Deviation)** | **69.3 (3.1)** | **68.4 (3.3)** | **68.7 (3.3)** |
| **Gender [units: Participants]** | | | |
| **Female** | **8** | **26** | **34** |
| **Male** | **16** | **25** | **41** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Renal Function by Glomerular Filtration Rate (GFR) Via Cockcroft-Gault Method [ Time Frame: Month 6 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Renal Function by Glomerular Filtration Rate (GFR) Via Cockcroft-Gault Method |
| **Measure Description** | The study was terminated prematurely and not powered for efficacy. |
| **Time Frame** | Month 6 |
| **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.** |
|---|
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | Description |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | Control Group | Everolimus Group |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Renal Function by Glomerular Filtration Rate (GFR) Via Cockcroft-Gault Method** | | |

**No statistical analysis provided for Renal Function by Glomerular Filtration Rate (GFR) Via Cockcroft-Gault Method**

2. Secondary: Renal Function by GFR Via Modification of Diet in Renal Diseases (MDRD) and Nankivell Method [ Time Frame: Month 6 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Renal Function by GFR Via Modification of Diet in Renal Diseases (MDRD) and Nankivell Method |
| **Measure Description** | The study was terminated prematurely and not powered for efficacy. |
| **Time Frame** | Month 6 |
| **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.** |
|---|
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | Description |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | Control Group | Everolimus Group |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Renal Function by GFR Via Modification of Diet in Renal Diseases (MDRD) and Nankivell Method** | | |

**No statistical analysis provided for Renal Function by GFR Via Modification of Diet in Renal Diseases (MDRD) and Nankivell Method**

3. Secondary: Renal Function by Serum Creatinine [ Time Frame: Months 6, 12, 24, 36, 48 and 60 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Renal Function by Serum Creatinine |
| **Measure Description** | The study was terminated prematurely and not powered for efficacy. |
| **Time Frame** | Months 6, 12, 24, 36, 48 and 60 |
| **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.** |
|---|
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | **Control Group** | **Everolimus Group** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Renal Function by Serum Creatinine** | | |

**No statistical analysis provided for Renal Function by Serum Creatinine**

4. Secondary: Biopsy Proven Acute Rejection (BPAR), Graft Loss and Death [ Time Frame: Months 6, 12, 24, 36, 48 and 60 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Biopsy Proven Acute Rejection (BPAR), Graft Loss and Death |
| **Measure Description** | The study was terminated prematurely and not powered for efficacy. |
| **Time Frame** | Months 6, 12, 24, 36, 48 and 60 |
| **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.** |
|---|
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | **Description** |
|---|---|

| | |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | Control Group | Everolimus Group |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Biopsy Proven Acute Rejection (BPAR), Graft Loss and Death** | | |

**No statistical analysis provided for Biopsy Proven Acute Rejection (BPAR), Graft Loss and Death**

5. Secondary: Occurrence of Treatment Failures [ Time Frame: Month 6 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Occurrence of Treatment Failures |
| **Measure Description** | The study was terminated prematurely and not powered for efficacy. |
| **Time Frame** | Month 6 |
| **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.** |
|---|
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | Control Group | Everolimus Group |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Occurrence of Treatment Failures** | | |

**No statistical analysis provided for Occurrence of Treatment Failures**

6. Secondary: Evolution of Renal Function (Creatinine Slope) [ Time Frame: Week 7, Month 6 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Evolution of Renal Function (Creatinine Slope) |
| **Measure Description** | The study was terminated prematurely and not powered for efficacy. |
| **Time Frame** | Week 7, Month 6 |
| **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.** |
|---|
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | **Control Group** | **Everolimus Group** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Evolution of Renal Function (Creatinine Slope)** | | |

**No statistical analysis provided for Evolution of Renal Function (Creatinine Slope)**

7. Secondary: CD25 Saturation on Lymphocytes [ Time Frame: Month 6 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | CD25 Saturation on Lymphocytes |
| **Measure Description** | No text entered. |
| **Time Frame** | Month 6 |
| **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.** |
|---|
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | **Description** |
|---|---|

| | |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | Control Group | Everolimus Group |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **CD25 Saturation on Lymphocytes** | | |

**No statistical analysis provided for CD25 Saturation on Lymphocytes**

8. Secondary: Number of Participants Who Experienced Adverse Events, Serious Adverse Events and Death [ Time Frame: Months 6, 12, 24, 36, 48 and 60 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Number of Participants Who Experienced Adverse Events, Serious Adverse Events and Death |
| **Measure Description** | Participants with adverse events (serious plus non-serious), serious adverse events and death were reported. |
| **Time Frame** | Months 6, 12, 24, 36, 48 and 60 |
| **Safety Issue** | Yes |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Randomized Safety Set: This set included all randomized participants who received at least one dose of study medication. |

**Reporting Groups**

| | Description |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | Control Group | Everolimus Group |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **24** | **51** |
| **Number of Participants Who Experienced Adverse Events, Serious Adverse Events and Death [units: Participants]** | | |
| **Adverse events (serious and non-serious)** | **21** | **50** |
| **Serious adverse events** | **11** | **28** |
| **Deaths** | **0** | **0** |

**No statistical analysis provided for Number of Participants Who Experienced Adverse Events, Serious Adverse Events and Death**

9. Secondary: Renal Function by GFR Over Time [ Time Frame: Months 12, 24, 36, 48 and 60 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Renal Function by GFR Over Time |
| **Measure Description** | No text entered. |
| **Time Frame** | Months 12, 24, 36, 48 and 60 |
| **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.** |
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | **Control Group** | **Everolimus Group** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Renal Function by GFR Over Time** | | |

**No statistical analysis provided for Renal Function by GFR Over Time**

10. Secondary: Renal Function by Proteinuria [ Time Frame: Months12, 24, 36, 48 and 60 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Renal Function by Proteinuria |
| **Measure Description** | No text entered. |
| **Time Frame** | Months12, 24, 36, 48 and 60 |
| **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.** |
| This outcome measure was not analyzed because a total of 244 completed subjects were needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done. |

**Reporting Groups**

| | Description |
|---|---|
| **Control Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Measured Values**

| | Control Group | Everolimus Group |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **0** | **0** |
| **Renal Function by Proteinuria** | | |

**No statistical analysis provided for Renal Function by Proteinuria**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **Control Goup** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Serious Adverse Events**

| | Control Goup | Everolimus Group |
|---|---|---|
| **Total, serious adverse events** | | |
| **# participants affected / at risk** | **11/24 (45.83%)** | **28/51 (54.90%)** |
| **Blood and lymphatic system disorders** | | |
| **ANAEMIA † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **2/51 (3.92%)** |
| **LEUKOPENIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **3/51 (5.88%)** |
| **PANCYTOPENIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **2/51 (3.92%)** |
| **Cardiac disorders** | | |
| **MITRAL VALVE INCOMPETENCE † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **0/51 (0.00%)** |

| | | |
|---|---|---|
| **Gastrointestinal disorders** | | |
| **ABDOMINAL MASS † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **APHTHOUS STOMATITIS † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **CROHN'S DISEASE † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **DIARRHOEA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **2/51 (3.92%)** |
| **ENTEROCOLITIS HAEMORRHAGIC † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **ILEUS PARALYTIC † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **INGUINAL HERNIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **General disorders** | | |
| **GENERAL PHYSICAL HEALTH DETERIORATION † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **PYREXIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **Immune system disorders** | | |
| **TRANSPLANT REJECTION † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **0/51 (0.00%)** |
| **Infections and infestations** | | |
| **BK VIRUS INFECTION † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **BRONCHOPULMONARY ASPERGILLOSIS † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **CYTOMEGALOVIRUS COLITIS † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **FEBRILE INFECTION † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **GASTROENTERITIS VIRAL † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **GENITAL HERPES † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **HEPATIC CYST INFECTION † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **0/51 (0.00%)** |
| **HERPES ZOSTER OTICUS † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **INFECTION † 1** | | |
| **# participants affected / at risk** | **2/24 (8.33%)** | **1/51 (1.96%)** |
| **PNEUMONIA † 1** | | |
| **# participants affected / at risk** | **2/24 (8.33%)** | **4/51 (7.84%)** |

| | | |
|---|---|---|
| **PYELONEPHRITIS ACUTE** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **URINARY TRACT INFECTION** † 1 | | |
| **# participants affected / at risk** | **3/24 (12.50%)** | **5/51 (9.80%)** |
| **UROSEPSIS** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **Injury, poisoning and procedural complications** | | |
| **GRAFT DYSFUNCTION** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **INCISIONAL HERNIA** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **POST PROCEDURAL HAEMORRHAGE** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **WOUND DEHISCENCE** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **Investigations** | | |
| **BLOOD CREATININE INCREASED** † 1 | | |
| **# participants affected / at risk** | **4/24 (16.67%)** | **5/51 (9.80%)** |
| **Metabolism and nutrition disorders** | | |
| **HYPOGLYCAEMIA** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | | |
| **BASAL CELL CARCINOMA** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **Nervous system disorders** | | |
| **FACIAL NERVE DISORDER** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **Renal and urinary disorders** | | |
| **ACUTE PRERENAL FAILURE** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **ANURIA** † 1 | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **0/51 (0.00%)** |
| **NEPHROSCLEROSIS** † 1 | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **0/51 (0.00%)** |
| **RENAL ARTERY STENOSIS** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **RENAL FAILURE ACUTE** † 1 | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **1/51 (1.96%)** |
| **URETERIC STENOSIS** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **2/51 (3.92%)** |
| **URINARY TRACT DISORDER** † 1 | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **Respiratory, thoracic and mediastinal disorders** | | |
| | | |

| | | |
|---|---|---|
| **DYSPNOEA EXERTIONAL † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |
| **PULMONARY ARTERIAL HYPERTENSION † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **0/51 (0.00%)** |
| **Vascular disorders** | | |
| **ARTERIOVENOUS FISTULA † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **1/51 (1.96%)** |
| **LYMPHOCELE † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **1/51 (1.96%)** |

† 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 Goup** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group continued with a CNI-based regimen of MPA and CsA. |
| **Everolimus Group** | During the pre-randomized treatment phase, all participants received a CNI-based regimen consisting of basiliximab, mycophenolic acid (MPA), cyclosporin A (CsA) and corticosteroids (optional). Upon randomization, participants in this group made a stepwise switch to a CNI-free regimen of everolimus and MPA. |

**Other Adverse Events**

| | **Control Goup** | **Everolimus Group** |
|---|---|---|
| **Total, other (not including serious) adverse events** | | |
| **# participants affected / at risk** | **15/24 (62.50%)** | **50/51 (98.04%)** |
| **Blood and lymphatic system disorders** | | |
| **ANAEMIA † 1** | | |
| **# participants affected / at risk** | **2/24 (8.33%)** | **6/51 (11.76%)** |
| **LEUKOPENIA † 1** | | |
| **# participants affected / at risk** | **4/24 (16.67%)** | **20/51 (39.22%)** |
| **Gastrointestinal disorders** | | |
| **APHTHOUS STOMATITIS † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **9/51 (17.65%)** |
| **CONSTIPATION † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **3/51 (5.88%)** |
| **DIARRHOEA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **10/51 (19.61%)** |

| | | |
|---|---|---|
| **FLATULENCE † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **4/51 (7.84%)** |
| **NAUSEA † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **3/51 (5.88%)** |
| **General disorders** | | |
| **OEDEMA PERIPHERAL † 1** | | |
| **# participants affected / at risk** | **7/24 (29.17%)** | **13/51 (25.49%)** |
| **PYREXIA † 1** | | |
| **# participants affected / at risk** | **4/24 (16.67%)** | **5/51 (9.80%)** |
| **Infections and infestations** | | |
| **CYTOMEGALOVIRUS INFECTION † 1** | | |
| **# participants affected / at risk** | **2/24 (8.33%)** | **4/51 (7.84%)** |
| **NASOPHARYNGITIS † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **5/51 (9.80%)** |
| **URINARY TRACT INFECTION † 1** | | |
| **# participants affected / at risk** | **6/24 (25.00%)** | **22/51 (43.14%)** |
| **Investigations** | | |
| **BLOOD CREATININE INCREASED † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **5/51 (9.80%)** |
| **Metabolism and nutrition disorders** | | |
| **HYPERLIPIDAEMIA † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **3/51 (5.88%)** |
| **HYPERURICAEMIA † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **4/51 (7.84%)** |
| **HYPOCALCAEMIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **3/51 (5.88%)** |
| **HYPOKALAEMIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **12/51 (23.53%)** |
| **HYPOMAGNESAEMIA † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **3/51 (5.88%)** |
| **HYPOPHOSPHATAEMIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **4/51 (7.84%)** |
| **IRON DEFICIENCY † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **5/51 (9.80%)** |
| **VITAMIN D DEFICIENCY † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **3/51 (5.88%)** |
| **Psychiatric disorders** | | |
| **INSOMNIA † 1** | | |
| **# participants affected / at risk** | **1/24 (4.17%)** | **3/51 (5.88%)** |
| **Renal and urinary disorders** | | |
| **PROTEINURIA † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **8/51 (15.69%)** |
| **Respiratory, thoracic and mediastinal disorders** | | |
| | | |

| | | |
|---|---|---|
| **DYSPNOEA † 1** | | |
| **# participants affected / at risk** | **3/24 (12.50%)** | **3/51 (5.88%)** |
| **PLEURAL EFFUSION † 1** | | |
| **# participants affected / at risk** | **0/24 (0.00%)** | **3/51 (5.88%)** |
| **Skin and subcutaneous tissue disorders** | | |
| **PRURITUS † 1** | | |
| **# participants affected / at risk** | **2/24 (8.33%)** | **1/51 (1.96%)** |
| **Vascular disorders** | | |
| **HYPERTENSION † 1** | | |
| **# participants affected / at risk** | **3/24 (12.50%)** | **6/51 (11.76%)** |

† 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:**

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: +1 (862) 778-1873

**No publications provided**

Responsible Party: Novartis ( Novartis Pharmaceuticals )
ClinicalTrials.gov Identifier: NCT00956293 History of Changes

| | |
|---|---|
| Other Study ID Numbers: | **CRAD001ADE19**<br>EudraCT-NO. 2008-005109-20<br>2008-005109-20 |
| Study First Received: | August 7, 2009 |
| Results First Received: | March 26, 2014 |
| Last Updated: | May 23, 2014 |
| Health Authority: | United States: Food and Drug Administration<br>Germany: Federal Institute for Drugs and Medical Devices |