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Trial record **1 of 1** for: CRAD001ANO02

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SCHEDULE - Scandinavian Heart Transplant Everolimus de Novo Study With Early Calcineurin Inhibitor (CNI) Avoidance (SCHEDULE)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01266148

First received: August 9, 2010
Last updated: May 15, 2015
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History of Changes

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Results First Received: April 11, 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 and Chronic Allograft Vasculopathy
Interventions:	Drug: Cyclosporine Drug: Mycophenolate mofetil Drug: Corticosteroids Drug: Everolimus Drug: Anti Thymocyte Globulin

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
115 patients (56 in the everolimus group, 59 in the control group) were randomized and received study treatment.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Group A (control) received treatment with Cyclosporine A (CsA), Mycophenolate mofetil (MMF), and corticosteroids. Group B (everolimus), received: low-dose CsA and everolimus, reduced dose MMF, and corticosteroids. After week 7-11, CsA was discontinued in Group B, while the standard triple-drug immunosuppressive regimen was maintained in Group A.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Participant Flow: Overall Study

	Everolimus	Control
STARTED	56	59
COMPLETED	49	56
NOT COMPLETED	7	3
Adverse Event	2	0
Ongoing rejection	1	0
2 2R rejections	1	0
Death	2	3
missing mGFR value + AE	1	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
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.
Total	Total of all reporting groups

Baseline Measures

	Everolimus	Control	Total
Number of Participants [units: participants]	56	59	115
Age [units: years] Mean (Standard Deviation)	51.02 (12.93)	51.47 (12.36)	51.25 (12.59)
Gender [units: participants]			
Female	17	14	31
Male	39	45	84

Outcome Measures

Hide All Outcome Measures

1. Primary: Measured Glomerular Filtration Rate (mGFR), 12 Months After Heart Transplantation [Time Frame: Week 52]

Measure Type	Primary
Measure Title	Measured Glomerular Filtration Rate (mGFR), 12 Months After Heart Transplantation

Measure Description	Measured Glomerular Filtration Rate (mGFR) describes the flow rate of filtered fluid through the kidney. GFR is equal to the clearance rate when any solute is freely filtered and is neither reabsorbed nor secreted by the kidneys. The rate therefore measured is the quantity of the substance in the urine that originated from a calculable volume of blood. Participants' urine was used for this assessment at week 52 after heart transplant.
Time Frame	Week 52
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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	**Control**
Number of Participants Analyzed [units: participants]	**51**	**56**
Measured Glomerular Filtration Rate (mGFR), 12 Months After Heart Transplantation [units: mGFR ml/min] Mean (Standard Deviation)	**79.8 (17.7)**	**61.5 (19.6)**

No statistical analysis provided for Measured Glomerular Filtration Rate (mGFR), 12 Months After Heart Transplantation

2. Secondary: Progression of Chronic Allograft Vasculopathy (CAV) Based on Maximal Intimal Thickness (MIT) From Baseline to Week 52 [Time Frame: Baseline and week 52]

Measure Type	Secondary
Measure Title	Progression of Chronic Allograft Vasculopathy (CAV) Based on Maximal Intimal Thickness (MIT) From Baseline to Week 52
Measure Description	The progression of chronic allograft vasculopathy (CAV) was assessed by intravascular ultrasound (IVUS) examinations and measured Maximal Intimal Thickness (MIT)(in mm). A major coronary epicardial artery (preferentially the left-anterior descending coronary artery) was imaged, and the MIT parameters were recorded at baseline and at week 52.
Time Frame	Baseline and week 52
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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	Control
Number of Participants Analyzed [units: participants]	**46**	**48**
Progression of Chronic Allograft Vasculopathy (CAV) Based on Maximal Intimal Thickness (MIT) From Baseline to Week 52 [units: mm] Mean (Standard Deviation)		
Baseline (Week 7)	**0.52 (0.22)**	**0.56 (0.24)**
Week 52	**0.55 (0.24)**	**0.65 (0.25)**

No statistical analysis provided for Progression of Chronic Allograft Vasculopathy (CAV) Based on Maximal Intimal Thickness (MIT) From Baseline to Week 52

3. Secondary: Progression of Chronic Allograft Vasculopathy (CAV) Based on Incidence of Chronic Allograft Vasculopathy (CAV) From Baseline to Week 52 [Time Frame: Baseline and week 52]

Measure Type	Secondary
Measure Title	Progression of Chronic Allograft Vasculopathy (CAV) Based on Incidence of Chronic Allograft Vasculopathy (CAV) From Baseline to Week 52
Measure Description	the progression of chronic allograft vasculopathy (CAV) assessed by intravascular ultrasound (IVUS) examinations, measured the incidence of CAV (in percent of patients) at baseline and at week 52. Incidence of CAV represents percent of patients having a MIT (maximal intima thickness) > 0.5 mm.
Time Frame	Baseline and week 52
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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	Control

Number of Participants Analyzed [units: participants]	**46**	**48**
Progression of Chronic Allograft Vasculopathy (CAV) Based on Incidence of Chronic Allograft Vasculopathy (CAV) From Baseline to Week 52 [units: Percentage of patients]		
No CAV at baseline (week 7)	**43.5**	**47.9**
CAV at baseline (week 7)	**56.5**	**52.1**
No CAV at week 52	**50**	**35.4**
CAV at week 52	**50**	**64.6**

No statistical analysis provided for Progression of Chronic Allograft Vasculopathy (CAV) Based on Incidence of Chronic Allograft Vasculopathy (CAV) From Baseline to Week 52

4. Secondary: Change in Calculated Glomerular Filtration Rate From Pre-transplantation to Week 52 [Time Frame: Day 1, weeks 7 to 11(baseline) and of week 52]

Measure Type	Secondary
Measure Title	Change in Calculated Glomerular Filtration Rate From Pre-transplantation to Week 52
Measure Description	Change in calculated glomerular filtration rate from pre-transplantation to week 52 was calculated according to the Modification of Diet in Renal Disease (MDRD) method. Measurements were taken prior to transplant (day 1), between weeks 7 to 11 and end week 52.
Time Frame	Day 1, weeks 7 to 11(baseline) and of week 52
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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	**Control**
Number of Participants Analyzed [units: participants]	**46**	**53**
Change in Calculated Glomerular Filtration Rate From Pre-transplantation to Week 52 [units: mGFR mL/min] Mean (Standard Deviation)		
Day 1 (n= 43, 47)	**-13.0 (28.2)**	**-12.6 (32.6)**
Weeks 7 to 11 (n= 46, 49)	**7.4 (32.6)**	**-6.8 (26.2)**
Week 52 (n= 42, 53)	**27.8 (49.9)**	**-8.0 (28.3)**

No statistical analysis provided for Change in Calculated Glomerular Filtration Rate From Pre-transplantation to Week 52

5. Secondary: Calculated Glomerular Filtration Rate From Pre-Transplantation to Week 52 [Time Frame: Day 1, weeks 7 to 11 and of week 52]

Measure Type	Secondary
Measure Title	Calculated Glomerular Filtration Rate From Pre-Transplantation to Week 52
Measure Description	Calculated Glomerular Filtration Rate from pre-transplantation to week 52 was calculated according to the Modification of Diet in Renal Disease (MDRD) method. Measurements were taken prior to transplant (day 1), between weeks 7 to 11 and end of week 52.
Time Frame	Day 1, weeks 7 to 11 and of week 52
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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	**Control**
Number of Participants Analyzed [units: participants]	**50**	**55**
Calculated Glomerular Filtration Rate From Pre-Transplantation to Week 52 [units: mGFR mL/min] Mean (Standard Deviation)		
Day 1 (n= 46, 48)	**65.4 (33.8)**	**66.1 (28.7)**
Weeks 7 to 11 (n=50, 51)	**84.9 (40.5)**	**69.6 (19.9)**
Week 52 (n= 45, 55)	**104.5 (54.0)**	**69.3 (20.4)**

No statistical analysis provided for Calculated Glomerular Filtration Rate From Pre-Transplantation to Week 52

6. Secondary: Number of Rejections Leading to Hemodynamic Compromise [Time Frame: 52 weeks]

Measure Type	Secondary
Measure Title	Number of Rejections Leading to Hemodynamic Compromise
Measure Description	Number of all rejections were recorded through the duration of the study with the intent to identify rejections leading to hemodynamic compromise.
Time Frame	52 weeks

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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	Control
Number of Participants Analyzed [units: participants]	**52**	**56**
Number of Rejections Leading to Hemodynamic Compromise [units: rejections]		
Total rejection	**185**	**128**
Treated rejection	**43**	**17**
Rejections with hemodynamic compromise	**0**	**0**

No statistical analysis provided for Number of Rejections Leading to Hemodynamic Compromise

7. Secondary: Occurrence of Treatment Failures up to 12 Months After Transplant [Time Frame: 52 weeks]

Measure Type	Secondary
Measure Title	Occurrence of Treatment Failures up to 12 Months After Transplant
Measure Description	Treatment failure was defined as the number of participants who died or lost their graft at any timepoint througout the duration of the study.
Time Frame	52 weeks
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.
The intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	Control
Number of Participants Analyzed [units: participants]	**56**	**59**
Occurrence of Treatment Failures up to 12 Months After Transplant [units: participants]		
Treatment failure (death)	**2**	**3**
Graff loss	**0**	**0**
Total treatment failures (graft loss + death	**2**	**3**

No statistical analysis provided for Occurrence of Treatment Failures up to 12 Months After Transplant

8. Secondary: Average Level of Protenuria at Week 52 [Time Frame: 52 weeks]

Measure Type	Secondary
Measure Title	Average Level of Protenuria at Week 52
Measure Description	Proteinuria is measured as the ratio of albumin/creatinine mg/mmol. Measurements were taken from participants urine samples.
Time Frame	52 weeks
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.
The safety sert include all randomized participants who received at least one dose of study medication and were able to provide urine samples at week 52.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	Control
Number of Participants Analyzed [units: participants]	**52**	**56**
Average Level of Protenuria at Week 52 [units: mg/mmol] Mean (Standard Deviation)	**7.2 (12.8)**	**1.2 (1.4)**

No statistical analysis provided for Average Level of Protenuria at Week 52

9. Secondary: Lipid Profile at 12 Months [Time Frame: 52 weeks]

Measure Type	Secondary

Measure Title	Lipid Profile at 12 Months
Measure Description	Total Cholesterol, LDL-Chol, HDL-Chol and TG at week 52. Measurements were taken via participants blood samples.
Time Frame	52 weeks
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 sert include all randomized participants who received at least one dose of study medication and had blood samples taken at week 52.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	**Control**
Number of Participants Analyzed [units: participants]	**53**	**56**
Lipid Profile at 12 Months [units: mmol/L] Mean (Standard Deviation)		
Total cholesterol	**5.3 (1.1)**	**5.1 (1.0)**
LDL-C	**2.9 (1.0)**	**2.8 (0.8)**
HDL-C	**1.6 (0.5)**	**1.6 (0.5)**

No statistical analysis provided for Lipid Profile at 12 Months

10. Secondary: Change in Quality of Life Assessed by SF-36 (Minnesota Living With Heart Failure Questionnaire ([MLHF)]) From Pre-transplant to Week 52 of Treatment [Time Frame: Pre transplant and 52 weeks]

Measure Type	Secondary
Measure Title	Change in Quality of Life Assessed by SF-36 (Minnesota Living With Heart Failure Questionnaire ([MLHF)]) From Pre-transplant to Week 52 of Treatment
Measure Description	Change in Quality of Life was assessed via the SF-36 (Minnesota Living with Heart Failure questionnaire ([MLHF)]) before transplant surgery and at week 52 of treatment. The SF-36 is a validated, self-administered questionnaire. The questionnaire, which includes 36 questions measures 8 dimensions of health: physical function, role-physical, bodily pain, general health, vitality, social function, role-emotional, and mental health. Scores can be summarized in 2 summary components assessing physical and mental health. Items in each dimension are coded, aggregated, summed, and transformed into a scale ranging from 0 (worse health) to 100 (best health).
Time Frame	Pre transplant and 52 weeks
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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria

causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	Control
Number of Participants Analyzed [units: participants]	**41**	**45**
Change in Quality of Life Assessed by SF-36 (Minnesota Living With Heart Failure Questionnaire ([MLHF])) From Pre-transplant to Week 52 of Treatment [units: Units on a scale] Mean (Standard Deviation)		
Physical Health pre- transplant	**30.8 (11.1)**	**32.9 (8.0)**
Physical Health at week 52	**48.8 (9.6)**	**48.8 (8.3)**
Mental Health pre- transplant	**46.2 (11.8)**	**38.7 (12.4)**
Mental Health at week 52	**51.5 (12.2)**	**53.9 (7.2)**

No statistical analysis provided for Change in Quality of Life Assessed by SF-36 (Minnesota Living With Heart Failure Questionnaire ([MLHF])) From Pre-transplant to Week 52 of Treatment

11. Secondary: Change in Quality of Life - Euro Quality of Life 5D (EQ-5D) [Time Frame: Pre transplant and 52 weeks]

Measure Type	Secondary
Measure Title	Change in Quality of Life - Euro Quality of Life 5D (EQ-5D)
Measure Description	Change in Quality of Life was assessed via the EQ-5D questionnaire which consists of: EQ-5D-5L descriptive system and EQ Visual Analogue scale (EQ VAS). The EQ-5D-5L comprises 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension has 5 levels (no problems, slight problems, moderate problems, severe problems, and extreme problems). The patient indicates his/her health state by checking the most appropriate statement. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions are combined in a 5-digit number describing the respondent's health state. The possible score is 1 to 5 where a lower number indicates improvement. The EQ VAS records the patient's self-rated health on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. The score is 0 to 100 where a higher score represents improvement.
Time Frame	Pre transplant and 52 weeks
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 intent to treat population includes the full analysis set patients with available data and without any major protocol deviations or criteria causing exclusion and for which data was available for analysis. Patients were analyzed according to the treatment to which they were

randomized.

Reporting Groups

	Description
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.
Control	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study.

Measured Values

	Everolimus	Control
Number of Participants Analyzed [units: participants]	**45**	**49**
Change in Quality of Life - Euro Quality of Life 5D (EQ-5D) [units: Units on a scale] Mean (Standard Deviation)		
EQ-5D-5L pre- transplant (n=45,49)	**0.5750 (0.3387)**	**0.5069 (0.3209)**
EQ-5D-5L at week 52 (n=41,44)	**0.8329 (0.2638)**	**0.8367 (0.2234)**
EQ VAS pre- transplant (n=41,48)	**46.0 (24.3)**	**38.9 (20.8)**
EQ VAS at week 52 (n=41,42)	**80.0 (15.0)**	**79.4 (11.5)**

No statistical analysis provided for Change in Quality of Life - Euro Quality of Life 5D (EQ-5D)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Controls	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.

Serious Adverse Events

	Controls	Everolimus
Total, serious adverse events		
# participants affected / at risk	**27/59 (45.76%)**	**27/56 (48.21%)**
Blood and lymphatic system disorders		
Neutropenia † [1]		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Cardiac disorders		
Arrhythmia † [1]		
# participants affected / at risk	**1/59 (1.69%)**	**1/56 (1.79%)**
Atrial fibrillation † [1]		

# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
Atrioventricular block complete † 1		
# participants affected / at risk	1/59 (1.69%)	0/56 (0.00%)
Cardiac arrest † 1		
# participants affected / at risk	1/59 (1.69%)	0/56 (0.00%)
Cardiac disorder † 1		
# participants affected / at risk	1/59 (1.69%)	3/56 (5.36%)
Palpitations † 1		
# participants affected / at risk	1/59 (1.69%)	0/56 (0.00%)
Gastrointestinal disorders		
Abdominal hernia † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
Constipation † 1		
# participants affected / at risk	1/59 (1.69%)	0/56 (0.00%)
Diarrhoea † 1		
# participants affected / at risk	3/59 (5.08%)	0/56 (0.00%)
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
Gastrointestinal pain † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
Large intestine perforation † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
Megacolon † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
Melaena † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
General disorders		
Device malfunction † 1		
# participants affected / at risk	1/59 (1.69%)	0/56 (0.00%)
Impaired healing † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)
Multi-organ failure † 1		
# participants affected / at risk	2/59 (3.39%)	1/56 (1.79%)
Pyrexia † 1		
# participants affected / at risk	3/59 (5.08%)	0/56 (0.00%)
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	1/59 (1.69%)	1/56 (1.79%)
Cytomegalovirus infection † 1		
# participants affected / at risk	3/59 (5.08%)	0/56 (0.00%)
Gastroenteritis † 1		
# participants affected / at risk	1/59 (1.69%)	0/56 (0.00%)
Gastroenteritis norovirus † 1		
# participants affected / at risk	0/59 (0.00%)	1/56 (1.79%)

Haemophilus infection † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Infection † 1		
# participants affected / at risk	**3/59 (5.08%)**	**1/56 (1.79%)**
Nasopharyngitis † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Osteomyelitis † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Pneumonia † 1		
# participants affected / at risk	**1/59 (1.69%)**	**5/56 (8.93%)**
Sepsis † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Urinary tract infection † 1		
# participants affected / at risk	**1/59 (1.69%)**	**1/56 (1.79%)**
Wound infection † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Injury, poisoning and procedural complications		
Graft complication † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Hip fracture † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Multiple fractures † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Rib fracture † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Diabetes mellitus † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Hyperglycaemia † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Musculoskeletal and connective tissue disorders		
Tendonitis † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Skin cancer † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Nervous system disorders		
Brain stem syndrome † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Cerebral haemorrhage † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Cerebrovascular accident † 1		

# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Epilepsy † 1		
# participants affected / at risk	**2/59 (3.39%)**	**0/56 (0.00%)**
Headache † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Presyncope † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Syncope † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Psychiatric disorders		
Confusional state † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Depression † 1		
# participants affected / at risk	**0/59 (0.00%)**	**2/56 (3.57%)**
Psychotic disorder † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Renal and urinary disorders		
Renal failure † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Renal failure acute † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Chylothorax † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Pleural effusion † 1		
# participants affected / at risk	**1/59 (1.69%)**	**2/56 (3.57%)**
Pleural haemorrhage † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Pneumonitis † 1		
# participants affected / at risk	**1/59 (1.69%)**	**1/56 (1.79%)**
Pneumothorax † 1		
# participants affected / at risk	**2/59 (3.39%)**	**0/56 (0.00%)**
Surgical and medical procedures		
Pericardial drainage † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**
Suture removal † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Vascular disorders		
Air embolism † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/56 (0.00%)**
Femoral artery occlusion † 1		

# participants affected / at risk	**0/59 (0.00%)**	**1/56 (1.79%)**

† Events were collected by systematic assessment
1 Term from vocabulary, 15.1

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
Controls	Participants received an immunosuppressive regimen consisting of CsA, MMF and CS throughout the study
Everolimus	Participants started immunosuppressive regimen consisting of low dose CsA, everolimus, MMF and CS. After week 11, the participants regimen consisted of everolimus, MMF and CS.

Other Adverse Events

	Controls	Everolimus
Total, other (not including serious) adverse events		
# participants affected / at risk	**53/59 (89.83%)**	**47/56 (83.93%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**5/59 (8.47%)**	**8/56 (14.29%)**
Leukopenia † 1		
# participants affected / at risk	**13/59 (22.03%)**	**11/56 (19.64%)**
Thrombocytopenia † 1		
# participants affected / at risk	**3/59 (5.08%)**	**2/56 (3.57%)**
Cardiac disorders		
Arrhythmia † 1		
# participants affected / at risk	**9/59 (15.25%)**	**6/56 (10.71%)**
Cardiac disorder † 1		
# participants affected / at risk	**1/59 (1.69%)**	**7/56 (12.50%)**
Pericardial effusion † 1		
# participants affected / at risk	**2/59 (3.39%)**	**4/56 (7.14%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**2/59 (3.39%)**	**10/56 (17.86%)**
General disorders		
Oedema † 1		
# participants affected / at risk	**1/59 (1.69%)**	**4/56 (7.14%)**
Oedema peripheral † 1		

# participants affected / at risk	10/59 (16.95%)	12/56 (21.43%)
Pyrexia † 1		
# participants affected / at risk	1/59 (1.69%)	3/56 (5.36%)
Infections and infestations		
Candidiasis † 1		
# participants affected / at risk	0/59 (0.00%)	3/56 (5.36%)
Cytomegalovirus infection † 1		
# participants affected / at risk	15/59 (25.42%)	3/56 (5.36%)
Herpes simplex † 1		
# participants affected / at risk	3/59 (5.08%)	1/56 (1.79%)
Infection † 1		
# participants affected / at risk	9/59 (15.25%)	10/56 (17.86%)
Nasopharyngitis † 1		
# participants affected / at risk	7/59 (11.86%)	9/56 (16.07%)
Pneumonia † 1		
# participants affected / at risk	1/59 (1.69%)	4/56 (7.14%)
Urinary tract infection † 1		
# participants affected / at risk	1/59 (1.69%)	5/56 (8.93%)
Metabolism and nutrition disorders		
Diabetes mellitus † 1		
# participants affected / at risk	0/59 (0.00%)	4/56 (7.14%)
Gout † 1		
# participants affected / at risk	3/59 (5.08%)	2/56 (3.57%)
Hypercholesterolaemia † 1		
# participants affected / at risk	2/59 (3.39%)	3/56 (5.36%)
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain † 1		
# participants affected / at risk	4/59 (6.78%)	5/56 (8.93%)
Osteoporosis † 1		
# participants affected / at risk	0/59 (0.00%)	3/56 (5.36%)
Pain in extremity † 1		
# participants affected / at risk	3/59 (5.08%)	3/56 (5.36%)
Nervous system disorders		
Headache † 1		
# participants affected / at risk	1/59 (1.69%)	3/56 (5.36%)
Tremor † 1		
# participants affected / at risk	8/59 (13.56%)	3/56 (5.36%)
Renal and urinary disorders		
Nephropathy toxic † 1		
# participants affected / at risk	3/59 (5.08%)	2/56 (3.57%)
Renal failure † 1		
# participants affected / at risk	3/59 (5.08%)	2/56 (3.57%)
Respiratory, thoracic and mediastinal disorders		
Pleural effusion † 1		

# participants affected / at risk	**7/59 (11.86%)**	**11/56 (19.64%)**
Pneumonitis † 1		
# participants affected / at risk	**3/59 (5.08%)**	**0/56 (0.00%)**
Pneumothorax † 1		
# participants affected / at risk	**1/59 (1.69%)**	**3/56 (5.36%)**
Skin and subcutaneous tissue disorders		
Acne † 1		
# participants affected / at risk	**1/59 (1.69%)**	**6/56 (10.71%)**
Hirsutism † 1		
# participants affected / at risk	**4/59 (6.78%)**	**0/56 (0.00%)**
Rash † 1		
# participants affected / at risk	**5/59 (8.47%)**	**5/56 (8.93%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**20/59 (33.90%)**	**10/56 (17.86%)**

† Events were collected by systematic assessment
1 Term from vocabulary, 15.1

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 pooled data (i.e.,data from all sites) in clinical trial or disclosure of trial results in their entirety.

Results Point of Contact:

Name/Title: Study director

Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Andreassen AK, Andersson B, Gustafsson F, Eiskjaer H, Radegran G, Gude E, Jansson K, Solbu D, Sigurdardottir V, Arora S, Dellgren G, Gullestad L; SCHEDULE Investigators. Everolimus initiation and early calcineurin inhibitor withdrawal in heart transplant recipients: a randomized trial. Am J Transplant. 2014 Aug;14(8):1828-38.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01266148 History of Changes
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