Trial record **1 of 1** for: CRAD001A2413
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ASCERTAIN: Assessment of Everolimus in Addition to Calcineurin Inhibitor Reduction in the Maintenance of Renal Transplant Recipients

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00170846

First received: September 9, 2005
Last updated: January 15, 2015
Last verified: March 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: December 17, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Renal Transplantation
Interventions:	Drug: Everolimus (RAD001) Drug: Calcineurin Inhibitors (CNI) Drug: Mycophenolate acid (MPA)/Azathioprine (AZA) Drug: Steroids

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
No text entered.

Reporting Groups

	Description
Group A: No RAD	Calcineurin Inhibitors (CNI) ± Mycophenolate Acid (MPA)/Azathioprine (AZA) ± Steroids
Group B : CNI Withdrawal	Initiation of everolimus (8-12 ng/mL) with discontinuation of CNI. Everolimus (RAD001) 4 mg initial daily dose.
Group C: CNI Reduction	Initiation of everolimus (3-8 ng/mL) with reduction by 70-90% in CNI blood levels. Everolimus (RAD001) 3 mg initial daily dose.

Participant Flow: Overall Study

	Group A: No RAD	Group B : CNI Withdrawal	Group C: CNI Reduction

STARTED	**123**	**127**	**144**
COMPLETED	**112**	**108**	**131**
NOT COMPLETED	**11**	**19**	**13**
Subject withdrew Informed Consent	**5**	**12**	**8**
Lost to Follow-up	**6**	**3**	**2**
Death	**0**	**3**	**3**
Reason Missing	**0**	**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
Group A: No RAD	Calcineurin Inhibitors (CNI) ± Mycophenolate Acid (MPA)/Azathioprine (AZA) ± Steroids
Group B : CNI Withdrawal	Initiation of everolimus (8-12 ng/mL) with discontinuation of CNI. Everolimus (RAD001) 4 mg initial daily dose.
Group C: CNI Reduction	Initiation of everolimus (3-8 ng/mL) with reduction by 70-90% in CNI blood levels. Everolimus (RAD001) 3 mg initial daily dose.
Total	Total of all reporting groups

Baseline Measures

	Group A: No RAD	**Group B : CNI Withdrawal**	**Group C: CNI Reduction**	**Total**
Number of Participants [units: participants]	**123**	**127**	**144**	**394**
Age [units: years] Mean (Standard Deviation)	**48.2 (12.18)**	**49.4 (11.81)**	**49.7 (12.95)**	**49.1 (12.34)**
Gender [units: participants]				
Female	**41**	**41**	**53**	**135**
Male	**82**	**86**	**91**	**259**
Time since transplantation [units: years] Mean (Standard Deviation)	**5.8 (4.14)**	**5.4 (4.28)**	**5.4 (3.99)**	**5.6 (4.13)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Renal Function Assessed by Measured GFR (mGFR) [Time Frame: 24 months]

Measure Type	Primary

Measure Title	Renal Function Assessed by Measured GFR (mGFR)
Measure Description	The acceptable methods for GFR measurement were Chromium 51-Ethylenediaminetetra acetic acid (Cr-EDTA), Technetium 99-Diethylenetriaminepentacetic acid (Tc-DTPA), Iohexol clearance Inuline clearance and Iothalamate clearance. The method should have been consistent for a given patient at every time point.
Time Frame	24 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The modified ITT population included all ITT patients who had mGFR or calculated GFR (cGFR) at Month 24 based on all values including those collected after discontinuation of study medication.

Reporting Groups

	Description
Group A: No RAD	Calcineurin Inhibitors (CNI) ± Mycophenolate Acid (MPA)/Azathioprine (AZA) ± Steroids
Group B : CNI Withdrawal	Initiation of everolimus (8-12 ng/mL) with discontinuation of CNI. Everolimus (RAD001) 4 mg initial daily dose.
Group C: CNI Reduction	Initiation of everolimus (3-8 ng/mL) with reduction by 70-90% in CNI blood levels. Everolimus (RAD001) 3 mg initial daily dose.

Measured Values

	Group A: No RAD	**Group B : CNI Withdrawal**	**Group C: CNI Reduction**
Number of Participants Analyzed [units: participants]	**103**	**94**	**109**
Renal Function Assessed by Measured GFR (mGFR) [units: mL/min/1.73m^2] Mean (Standard Deviation)	**46.02 (20.358)**	**48.00 (22.033)**	**46.60 (21.079)**

Statistical Analysis 1 for Renal Function Assessed by Measured GFR (mGFR)

Groups [1]	Group A: No RAD vs. Group B : CNI Withdrawal
Method [2]	ANCOVA
P Value [3]	0.6332
Difference in LS means [4]	1.1241
95% Confidence Interval	-3.5077 to 5.7559

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Renal Function Assessed by Measured GFR (mGFR)

Groups [1]	Group A: No RAD vs. Group C: CNI Reduction
Method [2]	ANCOVA
P Value [3]	0.7943
Difference in LS means [4]	0.5933
95% Confidence Interval	-3.8815 to 5.0682

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Number of Participants With Safety Parameters [Time Frame: 24 months]

Measure Type	Secondary
Measure Title	Number of Participants With Safety Parameters
Measure Description	The selected safety parameters (such as hypertension, hyperlipidemia, diabetes mellitus, anemia, malignancies) were derived based on adverse events preferred terms defined in the analysis plan.
Time Frame	24 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety Population. The Safety Population consisted of all randomized patients who received at least one dose of study drug and had at least one post-baseline safety assessment.

Reporting Groups

	Description
Group A: No RAD	Calcineurin Inhibitors (CNI) ± Mycophenolate Acid (MPA)/Azathioprine (AZA) ± Steroids
Group B : CNI Withdrawal	Initiation of everolimus (8-12 ng/mL) with discontinuation of CNI. Everolimus (RAD001) 4 mg initial daily dose.
Group C: CNI Reduction	Initiation of everolimus (3-8 ng/mL) with reduction by 70-90% in CNI blood levels. Everolimus (RAD001) 3 mg initial daily dose.

Measured Values

	Group A: No RAD	**Group B : CNI Withdrawal**	**Group C: CNI Reduction**
Number of Participants Analyzed [units: participants]	**123**	**127**	**144**
Number of Participants With Safety Parameters [units: Participants]			

Hypertension, Yes	**6**	**13**	**9**
Hypertension, No	**117**	**114**	**135**
Hyperlipidemia, Yes	**6**	**18**	**11**
Hyperlipidemia, No	**117**	**109**	**133**
Diabetes mellitus, Yes	**4**	**6**	**7**
Diabetes mellitus, No	**119**	**121**	**137**
Anemia, Yes	**25**	**45**	**46**
Anemia, No	**98**	**82**	**98**
Malignancies, Yes	**7**	**9**	**11**
Malignancies, No	**116**	**118**	**133**

No statistical analysis provided for Number of Participants With Safety Parameters

3. Post-Hoc: Change in mGFR by Baseline Calculated Creatinine Clearance (Cockcroft-Gault Formula) [Time Frame: Baseline and 24 months]

Measure Type	Post-Hoc
Measure Title	Change in mGFR by Baseline Calculated Creatinine Clearance (Cockcroft-Gault Formula)
Measure Description	Cockcroft-Gault formula (CrCl): Creatinine Clearance [mL/min] = CrCl (males) = (140 – A) * W / (72 * C) (males), CrCl (females) = CrCl (males) * 0.85, Where: • A is age [years] • W is body weight [kg] • C is the serum concentration of creatinine [mg/dL]
Time Frame	Baseline and 24 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Population. The per-protocol (PP) population consisted of the ITT patients excluding those patients with major protocol deviations and those patients who were not able to initiate their randomized regimens as scheduled.

Reporting Groups

	Description
Group A: No RAD	Calcineurin Inhibitors (CNI) ± Mycophenolate Acid (MPA)/Azathioprine (AZA) ± Steroids
Group B : CNI Withdrawal	Initiation of everolimus (8-12 ng/mL) with discontinuation of CNI. Everolimus (RAD001) 4 mg initial daily dose.
Group C: CNI Reduction	Initiation of everolimus (3-8 ng/mL) with reduction by 70-90% in CNI blood levels. Everolimus (RAD001) 3 mg initial daily dose.

Measured Values

	Group A: No RAD	**Group B : CNI Withdrawal**	**Group C: CNI Reduction**
Number of Participants Analyzed [units: participants]	**112**	**110**	**124**
Change in mGFR by Baseline Calculated Creatinine Clearance (Cockcroft-			

Gault Formula) [units: mL/min] Mean (Standard Deviation)			
Baseline CrCl(CG) ≤ 50 :(n= 32, 28, 32):- Change	**1.55 (12.833)**	**-5.75 (14.712)**	**0.82 (19.445)**
Baseline CrCl(CG) > 50 : (n=31, 29, 39):-Change	**-2.55 (19.562)**	**7.32 (21.051)**	**-0.24 (17.551)**

No statistical analysis provided for Change in mGFR by Baseline Calculated Creatinine Clearance (Cockcroft-Gault Formula)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Group A: No RAD	Calcineurin Inhibitors (CNI) ± Mycophenolate Acid (MPA)/Azathioprine (AZA) ± Steroids
Group B : CNI Withdrawal	Initiation of everolimus (8-12 ng/mL) with discontinuation of CNI. Everolimus (RAD001) 4 mg initial daily dose.
Group C: CNI Reduction	Initiation of everolimus (3-8 ng/mL) with reduction by 70-90% in CNI blood levels. Everolimus (RAD001) 3 mg initial daily dose.

Serious Adverse Events

	Group A: No RAD	**Group B : CNI Withdrawal**	**Group C: CNI Reduction**
Total, serious adverse events			
# participants affected / at risk	**52/123 (42.28%)**	**72/127 (56.69%)**	**78/144 (54.17%)**
Blood and lymphatic system disorders			
Anaemia † 1			
# participants affected / at risk	**3/123 (2.44%)**	**5/127 (3.94%)**	**3/144 (2.08%)**
Haemolytic uraemic syndrome † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**1/144 (0.69%)**
Iron deficiency anaemia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Leukopenia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**2/127 (1.57%)**	**0/144 (0.00%)**
Lymphadenopathy † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Pancytopenia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Thrombocytopenia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Cardiac disorders			
Acute coronary syndrome † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**

Acute myocardial infarction † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**2/144 (1.39%)**
Angina pectoris † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Aortic valve incompetence † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Atrial fibrillation † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**2/144 (1.39%)**
Bradycardia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Cardiac arrest † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Cardiac failure † 1			
# participants affected / at risk	**0/123 (0.00%)**	**2/127 (1.57%)**	**0/144 (0.00%)**
Cardiac failure acute † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Cardiac failure congestive † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Cardio-respiratory arrest † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Coronary artery stenosis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Left ventricular failure † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Tachycardia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Ear and labyrinth disorders			
Vertigo † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Eye disorders			
Papilloedema † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Gastrointestinal disorders			
Abdominal hernia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Abdominal pain † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**3/144 (2.08%)**
Abdominal pain upper † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**2/144 (1.39%)**
Colitis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Diarrhoea † 1			
# participants affected / at risk	**2/123 (1.63%)**	**6/127 (4.72%)**	**12/144 (8.33%)**
Dysphagia † 1			

# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Gastritis † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	1/144 (0.69%)
Gastritis erosive † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Gastrointestinal haemorrhage † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Gastrooesophageal reflux disease † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Glossodynia † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Nausea † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	2/144 (1.39%)
Pancreatitis acute † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Peritoneal haemorrhage † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Peritonitis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Reflux oesophagitis † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Vomiting † 1			
# participants affected / at risk	1/123 (0.81%)	5/127 (3.94%)	4/144 (2.78%)
General disorders			
Asthenia † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	3/144 (2.08%)
Chest discomfort † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Chest pain † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Cyst † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Death † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Face oedema † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Localised oedema † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Non-cardiac chest pain † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Oedema peripheral † 1			
# participants affected / at risk	1/123 (0.81%)	1/127 (0.79%)	3/144 (2.08%)
Pyrexia † 1			
# participants affected / at risk	1/123 (0.81%)	4/127 (3.15%)	11/144 (7.64%)

Sudden death † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Hepatobiliary disorders			
Cholecystitis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Cholecystitis acute † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Cholelithiasis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**2/144 (1.39%)**
Immune system disorders			
Kidney transplant rejection † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Transplant rejection † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Infections and infestations			
Abdominal infection † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Abscess fungal † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Abscess neck † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Anal abscess † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Breast abscess † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Bronchiectasis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Bronchitis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**3/144 (2.08%)**
Bronchitis viral † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Bronchopneumonia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Carbuncle † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Cardiac infection † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Catheter sepsis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Cellulitis † 1			
# participants affected / at risk	**2/123 (1.63%)**	**3/127 (2.36%)**	**4/144 (2.78%)**
Cryptosporidiosis infection † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Cytomegalovirus infection † 1			

# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Disseminated tuberculosis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Diverticulitis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Endocarditis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Enterocolitis infectious † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Escherichia infection † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Furuncle † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Gangrene † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Gastroenteritis † 1			
# participants affected / at risk	5/123 (4.07%)	4/127 (3.15%)	6/144 (4.17%)
Hepatitis B † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Hepatitis E † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Herpes zoster † 1			
# participants affected / at risk	0/123 (0.00%)	2/127 (1.57%)	1/144 (0.69%)
Infected sebaceous cyst † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Infection † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Influenza † 1			
# participants affected / at risk	0/123 (0.00%)	2/127 (1.57%)	0/144 (0.00%)
Lobar pneumonia † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Localised infection † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Lower respiratory tract infection † 1			
# participants affected / at risk	1/123 (0.81%)	1/127 (0.79%)	2/144 (1.39%)
Lower respiratory tract infection viral † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Lung infection † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Lung infection pseudomonal † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Meningitis † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Mucormycosis † 1			

# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Nail infection † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Nasopharyngitis † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Oophoritis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Oral infection † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Otitis media † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Perineal abscess † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Pneumonia † 1			
# participants affected / at risk	5/123 (4.07%)	2/127 (1.57%)	6/144 (4.17%)
Pneumonia bacterial † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Postoperative wound infection † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Pulmonary tuberculosis † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	1/144 (0.69%)
Pyelonephritis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	5/144 (3.47%)
Pyelonephritis acute † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Respiratory tract infection † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Salmonella sepsis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Sepsis † 1			
# participants affected / at risk	1/123 (0.81%)	3/127 (2.36%)	2/144 (1.39%)
Sialoadenitis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Sinusitis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Skin infection † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Tooth abscess † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Tuberculosis bladder † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Tuberculosis of genitourinary system † 1			
# participants affected / at risk	1/123 (0.81%)	1/127 (0.79%)	0/144 (0.00%)
Upper respiratory tract infection † 1			
# participants affected / at risk	0/123 (0.00%)	4/127 (3.15%)	1/144 (0.69%)

Urethral abscess † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Urinary tract infection † 1			
# participants affected / at risk	**6/123 (4.88%)**	**5/127 (3.94%)**	**10/144 (6.94%)**
Urosepsis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**1/144 (0.69%)**
Varicella † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Viral infection † 1			
# participants affected / at risk	**1/123 (0.81%)**	**2/127 (1.57%)**	**1/144 (0.69%)**
Wound infection † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Injury, poisoning and procedural complications			
Arteriovenous fistula site complication † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Arteriovenous fistula thrombosis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**1/144 (0.69%)**
Chronic allograft nephropathy † 1			
# participants affected / at risk	**1/123 (0.81%)**	**3/127 (2.36%)**	**0/144 (0.00%)**
Complications of transplanted kidney † 1			
# participants affected / at risk	**1/123 (0.81%)**	**2/127 (1.57%)**	**1/144 (0.69%)**
Concussion † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Femur fracture † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Hand fracture † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Limb injury † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Muscle injury † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Post procedural complication † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Post procedural haematuria † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**1/144 (0.69%)**
Postoperative wound complication † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Procedural vomiting † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Renal graft loss † 1			
# participants affected / at risk	**4/123 (3.25%)**	**3/127 (2.36%)**	**9/144 (6.25%)**
Rib fracture † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Subdural haematoma † 1			

# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Investigations			
Blood creatine phosphokinase MB increased † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Blood creatine phosphokinase increased † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Blood creatinine increased † 1			
# participants affected / at risk	7/123 (5.69%)	7/127 (5.51%)	4/144 (2.78%)
Blood folate decreased † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Blood urea increased † 1			
# participants affected / at risk	1/123 (0.81%)	1/127 (0.79%)	0/144 (0.00%)
Blood uric acid increased † 1			
# participants affected / at risk	2/123 (1.63%)	0/127 (0.00%)	0/144 (0.00%)
Protein urine † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Tuberculin test positive † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Urine output decreased † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Vitamin B12 decreased † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Weight decreased † 1			
# participants affected / at risk	0/123 (0.00%)	2/127 (1.57%)	1/144 (0.69%)
White blood cell count decreased † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Metabolism and nutrition disorders			
Acidosis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Decreased appetite † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Dehydration † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	3/144 (2.08%)
Diabetes mellitus † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Diabetes mellitus inadequate control † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	1/144 (0.69%)
Fluid overload † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Gout † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Hypercalcaemia † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	1/144 (0.69%)
Hyperglycaemia † 1			

# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Hypocalcaemia † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Hypoglycaemia † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Hypokalaemia † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Hyponatraemia † 1			
# participants affected / at risk	0/123 (0.00%)	2/127 (1.57%)	0/144 (0.00%)
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Back pain † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Bursitis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Musculoskeletal chest pain † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	1/144 (0.69%)
Myositis ossificans † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Osteitis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Osteonecrosis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma † 1			
# participants affected / at risk	1/123 (0.81%)	2/127 (1.57%)	4/144 (2.78%)
Basosquamous carcinoma of skin † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Benign uterine neoplasm † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Bowen's disease † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	2/144 (1.39%)
Breast cancer † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Lip neoplasm malignant stage unspecified † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Lung neoplasm malignant † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Malignant melanoma † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Metastatic malignant melanoma † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)

Prostate cancer † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**1/144 (0.69%)**
Renal cell carcinoma † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Seborrhoeic keratosis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Squamous cell carcinoma † 1			
# participants affected / at risk	**0/123 (0.00%)**	**3/127 (2.36%)**	**0/144 (0.00%)**
Squamous cell carcinoma of skin † 1			
# participants affected / at risk	**1/123 (0.81%)**	**1/127 (0.79%)**	**2/144 (1.39%)**
Thyroid cancer † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Transitional cell carcinoma † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Uterine leiomyoma † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Nervous system disorders			
Benign intracranial hypertension † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Brain stem infarction † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Cerebral infarction † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Convulsion † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Dizziness † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Headache † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Hemiplegia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Ischaemic stroke † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Lethargy † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**1/144 (0.69%)**
Loss of consciousness † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Nerve compression † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Partial seizures † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Syncope † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Tremor † 1			

# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Vocal cord paralysis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Renal and urinary disorders			
Azotaemia † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Glomerulonephritis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Haematuria † 1			
# participants affected / at risk	2/123 (1.63%)	1/127 (0.79%)	2/144 (1.39%)
Hydronephrosis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Nephrectasia † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Nephrotic syndrome † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Proteinuria † 1			
# participants affected / at risk	1/123 (0.81%)	3/127 (2.36%)	0/144 (0.00%)
Renal failure † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Renal failure acute † 1			
# participants affected / at risk	2/123 (1.63%)	1/127 (0.79%)	1/144 (0.69%)
Renal impairment † 1			
# participants affected / at risk	0/123 (0.00%)	3/127 (2.36%)	2/144 (1.39%)
Tubulointerstitial nephritis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Urethral obstruction † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Urinary bladder haemorrhage † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Vesicoureteric reflux † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Reproductive system and breast disorders			
Amenorrhoea † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Endometriosis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Epididymitis † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Ovarian cyst † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)

Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Bronchial disorder † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Cough † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Dysphonia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Dyspnoea † 1			
# participants affected / at risk	**0/123 (0.00%)**	**2/127 (1.57%)**	**3/144 (2.08%)**
Interstitial lung disease † 1			
# participants affected / at risk	**0/123 (0.00%)**	**2/127 (1.57%)**	**2/144 (1.39%)**
Lung disorder † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Organising pneumonia † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Pneumonitis † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**1/144 (0.69%)**
Pulmonary congestion † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Pulmonary embolism † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**2/144 (1.39%)**
Pulmonary oedema † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Tachypnoea † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Skin and subcutaneous tissue disorders			
Dermatitis contact † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Eczema † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Erythema † 1			
# participants affected / at risk	**0/123 (0.00%)**	**1/127 (0.79%)**	**0/144 (0.00%)**
Skin oedema † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Vascular disorders			
Aortic aneurysm † 1			
# participants affected / at risk	**0/123 (0.00%)**	**0/127 (0.00%)**	**1/144 (0.69%)**
Arterial stenosis † 1			
# participants affected / at risk	**1/123 (0.81%)**	**0/127 (0.00%)**	**0/144 (0.00%)**
Deep vein thrombosis † 1			

# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	2/144 (1.39%)
Extremity necrosis † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Haematoma † 1			
# participants affected / at risk	0/123 (0.00%)	1/127 (0.79%)	0/144 (0.00%)
Hypertension † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Hypertensive crisis † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Hypotension † 1			
# participants affected / at risk	0/123 (0.00%)	0/127 (0.00%)	1/144 (0.69%)
Iliac artery stenosis † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)
Peripheral vascular disorder † 1			
# participants affected / at risk	2/123 (1.63%)	1/127 (0.79%)	0/144 (0.00%)
Varicose vein † 1			
# participants affected / at risk	1/123 (0.81%)	0/127 (0.00%)	0/144 (0.00%)

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

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Group A: No RAD	Calcineurin Inhibitors (CNI) ± Mycophenolate Acid (MPA)/Azathioprine (AZA) ± Steroids
Group B : CNI Withdrawal	Initiation of everolimus (8-12 ng/mL) with discontinuation of CNI. Everolimus (RAD001) 4 mg initial daily dose.
Group C: CNI Reduction	Initiation of everolimus (3-8 ng/mL) with reduction by 70-90% in CNI blood levels. Everolimus (RAD001) 3 mg initial daily dose.

Other Adverse Events

	Group A: No RAD	Group B : CNI Withdrawal	Group C: CNI Reduction
Total, other (not including serious) adverse events			
# participants affected / at risk	97/123 (78.86%)	116/127 (91.34%)	126/144 (87.50%)
Blood and lymphatic system disorders			
Anaemia † 1			
# participants affected / at risk	22/123 (17.89%)	42/127 (33.07%)	40/144 (27.78%)
Leukopenia † 1			

# participants affected / at risk	5/123 (4.07%)	10/127 (7.87%)	3/144 (2.08%)
Thrombocytopenia † 1			
# participants affected / at risk	1/123 (0.81%)	10/127 (7.87%)	4/144 (2.78%)
Gastrointestinal disorders			
Aphthous stomatitis † 1			
# participants affected / at risk	2/123 (1.63%)	22/127 (17.32%)	9/144 (6.25%)
Diarrhoea † 1			
# participants affected / at risk	20/123 (16.26%)	36/127 (28.35%)	30/144 (20.83%)
Mouth ulceration † 1			
# participants affected / at risk	1/123 (0.81%)	15/127 (11.81%)	8/144 (5.56%)
Nausea † 1			
# participants affected / at risk	7/123 (5.69%)	9/127 (7.09%)	7/144 (4.86%)
Vomiting † 1			
# participants affected / at risk	7/123 (5.69%)	7/127 (5.51%)	9/144 (6.25%)
General disorders			
Oedema † 1			
# participants affected / at risk	0/123 (0.00%)	8/127 (6.30%)	6/144 (4.17%)
Oedema peripheral † 1			
# participants affected / at risk	12/123 (9.76%)	33/127 (25.98%)	37/144 (25.69%)
Pyrexia † 1			
# participants affected / at risk	6/123 (4.88%)	15/127 (11.81%)	16/144 (11.11%)
Infections and infestations			
Bronchitis † 1			
# participants affected / at risk	7/123 (5.69%)	6/127 (4.72%)	6/144 (4.17%)
Nasopharyngitis † 1			
# participants affected / at risk	8/123 (6.50%)	9/127 (7.09%)	13/144 (9.03%)
Upper respiratory tract infection † 1			
# participants affected / at risk	16/123 (13.01%)	11/127 (8.66%)	15/144 (10.42%)
Urinary tract infection † 1			
# participants affected / at risk	10/123 (8.13%)	20/127 (15.75%)	18/144 (12.50%)
Investigations			
Blood creatine phosphokinase increased † 1			
# participants affected / at risk	2/123 (1.63%)	7/127 (5.51%)	3/144 (2.08%)
Blood creatinine increased † 1			
# participants affected / at risk	15/123 (12.20%)	11/127 (8.66%)	10/144 (6.94%)
Metabolism and nutrition disorders			
Decreased appetite † 1			
# participants affected / at risk	2/123 (1.63%)	7/127 (5.51%)	3/144 (2.08%)
Gout † 1			
# participants affected / at risk	7/123 (5.69%)	4/127 (3.15%)	6/144 (4.17%)
Hypercholesterolaemia † 1			
# participants affected / at risk	5/123 (4.07%)	18/127 (14.17%)	24/144 (16.67%)
Hyperlipidaemia † 1			
# participants affected / at risk	6/123 (4.88%)	18/127 (14.17%)	11/144 (7.64%)

Hypertriglyceridaemia † 1			
# participants affected / at risk	**2/123 (1.63%)**	**6/127 (4.72%)**	**11/144 (7.64%)**
Hypokalaemia † 1			
# participants affected / at risk	**3/123 (2.44%)**	**12/127 (9.45%)**	**1/144 (0.69%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**7/123 (5.69%)**	**5/127 (3.94%)**	**9/144 (6.25%)**
Back pain † 1			
# participants affected / at risk	**7/123 (5.69%)**	**1/127 (0.79%)**	**2/144 (1.39%)**
Pain in extremity † 1			
# participants affected / at risk	**8/123 (6.50%)**	**3/127 (2.36%)**	**11/144 (7.64%)**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**5/123 (4.07%)**	**4/127 (3.15%)**	**9/144 (6.25%)**
Headache † 1			
# participants affected / at risk	**5/123 (4.07%)**	**7/127 (5.51%)**	**12/144 (8.33%)**
Renal and urinary disorders			
Proteinuria † 1			
# participants affected / at risk	**11/123 (8.94%)**	**18/127 (14.17%)**	**19/144 (13.19%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**9/123 (7.32%)**	**18/127 (14.17%)**	**15/144 (10.42%)**
Dyspnoea † 1			
# participants affected / at risk	**1/123 (0.81%)**	**9/127 (7.09%)**	**7/144 (4.86%)**
Oropharyngeal pain † 1			
# participants affected / at risk	**3/123 (2.44%)**	**6/127 (4.72%)**	**9/144 (6.25%)**
Skin and subcutaneous tissue disorders			
Acne † 1			
# participants affected / at risk	**1/123 (0.81%)**	**16/127 (12.60%)**	**3/144 (2.08%)**
Pruritus † 1			
# participants affected / at risk	**1/123 (0.81%)**	**7/127 (5.51%)**	**5/144 (3.47%)**
Rash † 1			
# participants affected / at risk	**1/123 (0.81%)**	**20/127 (15.75%)**	**12/144 (8.33%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**5/123 (4.07%)**	**12/127 (9.45%)**	**8/144 (5.56%)**
Hypotension † 1			
# participants affected / at risk	**1/123 (0.81%)**	**7/127 (5.51%)**	**3/144 (2.08%)**

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

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00170846 History of Changes
Other Study ID Numbers:	**CRAD001A2413**
Study First Received:	September 9, 2005
Results First Received:	December 17, 2010
Last Updated:	January 15, 2015
Health Authority:	Italy: National Monitoring Centre for Clinical Trials - Ministry of Health