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Trial record **1 of 1** for: CRAD001HDE10

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Preservation of Renal Function in Liver Transplant Recipients With Certican Therapy

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00378014

First received: September 15, 2006
Last updated: January 19, 2015
Last verified: January 2015
History of Changes

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Results First Received: January 16, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Liver Transplantation
Interventions:	Drug: everolimus Drug: basiliximab Drug: CNI

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 core study consisted of 2 periods: 1) during the first one-month period, 276 eligible participants received the same CNI-based immunosuppressive therapy prior to randomization; 2) during the second 11-month study period, 203 participants eligible participants were randomized in a 1:1 ratio to one of the two treatment arms.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Participant Flow for 2 periods

Period 1: Core (Randomization to Month 11)

	Everolimus	Calcineurin Inhibitor (CNI)
STARTED	101	102
Intent-to-treat (ITT) Population	96 [1]	98 [1]
COMPLETED	87	90
NOT COMPLETED	14	12
Adverse Event	1	0
Graft loss	1	2
Death	5	3
Administrative Problems	2	2
Lost to Follow-up	0	1
Withdrawal by Subject	5	2
Protocol deviation	0	1
Lack of Efficacy	0	1

[1] ITT contained all randomized patients who had at least one post baseline GFR measurement.

Period 2: Extension (Month 12 to Month 59)

	Everolimus	Calcineurin Inhibitor (CNI)
STARTED	41	40
COMPLETED	27	26
NOT COMPLETED	14	14
Adverse Event	8	7
Death	1	2
Administrative problems	1	0
Lost to Follow-up	1	1
Withdrawal by Subject	0	3
Lack of Efficacy	3	1

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	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice
Total	Total of all reporting groups

Baseline Measures

	Everolimus	Calcineurin Inhibitor (CNI)	Total
Number of Participants [units: participants]	**96**	**98**	**194**
Age [units: Years] Mean (Standard Deviation)	**52.3 (9.9)**	**52.9 (10.1)**	**52.6 (1)**
Gender [units: Participants]			
Female	**42**	**30**	**72**
Male	**54**	**68**	**122**

Outcome Measures

Hide All Outcome Measures

1. Primary: Calculated Glomerular Filtration Rate (cGFR) [Time Frame: Month 11]

Measure Type	Primary
Measure Title	Calculated Glomerular Filtration Rate (cGFR)
Measure Description	This outcome measure evaluated renal function by assessing the calculated GFR based on the Cockcroft-Gault formula.
Time Frame	Month 11
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.
ITT

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	Calcineurin Inhibitor (CNI)
Number of Participants Analyzed [units: participants]	**96**	**98**
Calculated Glomerular Filtration Rate (cGFR) [units: mL/min] Mean (Standard Deviation)	**87.9 (32.0)**	**84.1 (34.9)**

No statistical analysis provided for Calculated Glomerular Filtration Rate (cGFR)

2. Secondary: Incidence of Efficacy Failure [Time Frame: Month 11]

Measure Type	Secondary
Measure Title	Incidence of Efficacy Failure
Measure Description	Efficacy failure was defined as the composite endpoint of biopsy-proven acute rejection (BPAR), graft loss, death, lost to follow-up (from any reason), whichever occurred first. Incidence of efficacy failure was estimated using crude rate estimation (relative frequency).
Time Frame	Month 11
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.
ITT

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	**Calcineurin Inhibitor (CNI)**
Number of Participants Analyzed [units: participants]	**96**	**98**
Incidence of Efficacy Failure [units: Percentage of participants]	**20.8**	**20.4**

No statistical analysis provided for Incidence of Efficacy Failure

3. Secondary: Incidence of the Need for a Change in the Immunosuppressive Regimen [Time Frame: Month 11]

Measure Type	Secondary
Measure Title	Incidence of the Need for a Change in the Immunosuppressive Regimen
Measure Description	The incidence of any changes in the immunosuppressive regimen other than allowed in the study protocol (for example, introduction of Mycophenolic acid (MPA) or sirolimus) was estimated using crude rate estimation (relative frequency).
Time Frame	Month 11
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.
ITT

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice

Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	Calcineurin Inhibitor (CNI)
Number of Participants Analyzed [units: participants]	**96**	**98**
Incidence of the Need for a Change in the Immunosuppressive Regimen [units: Percentage of participants]	**80.2**	**73.5**

No statistical analysis provided for Incidence of the Need for a Change in the Immunosuppressive Regimen

4. Secondary: Renal Function (cGFR) [Time Frame: Month 5]

Measure Type	Secondary
Measure Title	Renal Function (cGFR)
Measure Description	This outcome measure evaluated renal function by assessing the calculated GFR based on the Cockcroft-Gault formula.
Time Frame	Month 5
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.
ITT

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	Calcineurin Inhibitor (CNI)
Number of Participants Analyzed [units: participants]	**96**	**98**
Renal Function (cGFR) [units: mL/min] Mean (Standard Deviation)	**88.7 (31.0)**	**82.9 (29.4)**

No statistical analysis provided for Renal Function (cGFR)

5. Secondary: Incidence of Treated BPAR [Time Frame: Month 11]

Measure Type	Secondary
Measure Title	Incidence of Treated BPAR
Measure Description	The incidence of treated BPAR was estimated using crude rate estimation (relative frequency).

Time Frame	Month 11
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.
ITT

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	**Calcineurin Inhibitor (CNI)**
Number of Participants Analyzed [units: participants]	**96**	**98**
Incidence of Treated BPAR [units: Percentage of Participants]	**13.5**	**10.2**

No statistical analysis provided for Incidence of Treated BPAR

6. Secondary: Patient and Graft Survival [Time Frame: Month 11]

Measure Type	Secondary
Measure Title	Patient and Graft Survival
Measure Description	Patient survival was defined as the time from date of randomization to date of death from any cause. If a patient was not known to have died, patient survival was censored as the date of last contact. Graft survival was defined as the time from the date of randomization to the date of graft loss. If a patient was not known to suffer from a graft loss or died without graft loss, time to graft loss was censored with date of last contact or date of death, respectively. Patient and graft survival were analyzed using the Kaplan Meier method.
Time Frame	Month 11
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.
ITT

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	Calcineurin Inhibitor (CNI)
Number of Participants Analyzed [units: participants]	**96**	**98**
Patient and Graft Survival [units: Percentage of Participants]		
Death	**4.3**	**4.1**
Graft loss	**2.2**	**2.1**

No statistical analysis provided for Patient and Graft Survival

7. Secondary: Hepatitis C Virus (HCV) Replication in HCV-positive Patients [Time Frame: Baseline, Month 5]

Measure Type	Secondary
Measure Title	Hepatitis C Virus (HCV) Replication in HCV-positive Patients
Measure Description	HCV ribonucleic acid (RNA) was measured by real time reverse transcriptase polymerase chain reaction (PCR; copies per mL).
Time Frame	Baseline, Month 5
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.
ITT

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	Calcineurin Inhibitor (CNI)
Number of Participants Analyzed [units: participants]	**96**	**98**
Hepatitis C Virus (HCV) Replication in HCV-positive Patients [units: Percentage of participants]		
Baseline, negative	**64.5**	**55.3**
Baseline, positive	**0.0**	**0.0**
Baseline, not done	**35.5**	**44.7**
Month 5, negative	**62.9**	**38.2**
Month 5, positive	**1.6**	**13.2**
Month 5, not done	**35.5**	**48.7**

No statistical analysis provided for Hepatitis C Virus (HCV) Replication in HCV-positive Patients

8. Secondary: Number of Patients Who Experienced Adverse Events, Serious Adverse Events and Death [Time Frame: From randomization to Month 11]

Measure Type	Secondary
Measure Title	Number of Patients Who Experienced Adverse Events, Serious Adverse Events and Death
Measure Description	Patients with all (serious and non-serious) adverse events, serious adverse events and death were reported.
Time Frame	From randomization to Month 11
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.
Safety population: This set included all randomized patients with at least one post-baseline measurement of GFR.

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	**Calcineurin Inhibitor (CNI)**
Number of Participants Analyzed [units: participants]	**101**	**102**
Number of Patients Who Experienced Adverse Events, Serious Adverse Events and Death [units: Number of participants]		
Adverse Events (serious and non-serious)	**98**	**96**
Serious Adverse Events	**67**	**58**
Deaths	**4**	**4**

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

9. Secondary: Number of Patients Who Experienced Adverse Events, Serious Adverse Events and Death [Time Frame: Month 12 to Month 59 post-baseline]

Measure Type	Secondary
Measure Title	Number of Patients Who Experienced Adverse Events, Serious Adverse Events and Death
Measure Description	Patients with all (serious and non-serious) adverse events, serious adverse events and death were reported.
Time Frame	Month 12 to Month 59 post-baseline
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.
Safety population: This set included all randomized patients with at least one post-baseline measurement of GFR.

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Measured Values

	Everolimus	Calcineurin Inhibitor (CNI)
Number of Participants Analyzed [units: participants]	**41**	**40**
Number of Patients Who Experienced Adverse Events, Serious Adverse Events and Death [units: Number of participants]		
Adverse Events (serious and non-serious)	**41**	**40**
Serious Adverse Events	**26**	**28**
Deaths	**1**	**2**

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

10. Secondary: Incidence of Renal Deterioration [Time Frame: Baseline, Month 11]

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

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice
Extension Period - Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Extension Period - CNI	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice

Serious Adverse Events

	Everolimus	Calcineurin Inhibitor (CNI)	Extension Period - Everolimus	Extension Period - CNI
Total, serious adverse events				
# participants affected / at risk	**67/101 (66.34%)**	**58/102 (56.86%)**	**26/41 (63.41%)**	**28/40 (70.00%)**
Blood and lymphatic system disorders				

ANAEMIA † [1]				
# participants affected / at risk	3/101 (2.97%)	2/102 (1.96%)	0/41 (0.00%)	1/40 (2.50%)
DISSEMINATED INTRAVASCULAR COAGULATION † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
HAEMOLYTIC URAEMIC SYNDROME † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
LEUKOPENIA † [1]				
# participants affected / at risk	4/101 (3.96%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
NEUTROPENIA † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
PANCYTOPENIA † [1]				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
THROMBOTIC MICROANGIOPATHY † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
Cardiac disorders				
ACUTE MYOCARDIAL INFARCTION † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
ARRHYTHMIA † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
ATRIAL FIBRILLATION † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
ATRIOVENTRICULAR BLOCK † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
BUNDLE BRANCH BLOCK RIGHT † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
CARDIAC ARREST † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
CARDIAC FAILURE † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CARDIAC FAILURE ACUTE † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
MYOCARDIAL INFARCTION † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PERICARDIAL EFFUSION † [1]				
# participants affected / at risk	2/101 (1.98%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
TACHYCARDIA † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
TORSADE DE POINTES † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
Ear and labyrinth disorders				
VERTIGO † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
Endocrine disorders				
GOITRE † [1]				

# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HYPERTHYROIDISM † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
TOXIC NODULAR GOITRE † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
Eye disorders				
MACULAR OEDEMA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
OCULAR ICTERUS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
PAPILLOEDEMA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
RETINAL HAEMORRHAGE † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
RETINAL VEIN OCCLUSION † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
RETINITIS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
Gastrointestinal disorders				
ABDOMINAL HERNIA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
ABDOMINAL PAIN † 1				
# participants affected / at risk	4/101 (3.96%)	2/102 (1.96%)	0/41 (0.00%)	0/40 (0.00%)
ANAL PROLAPSE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
ASCITES † 1				
# participants affected / at risk	0/101 (0.00%)	2/102 (1.96%)	1/41 (2.44%)	1/40 (2.50%)
COELIAC ARTERY STENOSIS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
CROHN'S DISEASE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
DIARRHOEA † 1				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
DYSPHAGIA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
GASTRITIS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
GASTRITIS HAEMORRHAGIC † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
GASTROINTESTINAL HAEMORRHAGE † 1				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
GASTROINTESTINAL NECROSIS † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
ILEUS † 1				

# participants affected / at risk	0/101 (0.00%)	2/102 (1.96%)	1/41 (2.44%)	0/40 (0.00%)
ILEUS PARALYTIC † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
INGUINAL HERNIA † 1				
# participants affected / at risk	2/101 (1.98%)	1/102 (0.98%)	1/41 (2.44%)	0/40 (0.00%)
INTESTINAL DILATATION † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
INTESTINAL HAEMORRHAGE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
MALABSORPTION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
MECHANICAL ILEUS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
NAUSEA † 1				
# participants affected / at risk	1/101 (0.99%)	2/102 (1.96%)	0/41 (0.00%)	1/40 (2.50%)
OESOPHAGEAL VARICES HAEMORRHAGE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
PANCREATIC CYST † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PANCREATITIS † 1				
# participants affected / at risk	0/101 (0.00%)	3/102 (2.94%)	0/41 (0.00%)	0/40 (0.00%)
PANCREATITIS ACUTE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
SMALL INTESTINAL OBSTRUCTION † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
SMALL INTESTINAL STENOSIS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
SUBILEUS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
UMBILICAL HERNIA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
VOMITING † 1				
# participants affected / at risk	2/101 (1.98%)	1/102 (0.98%)	0/41 (0.00%)	2/40 (5.00%)
General disorders				
ASTHENIA † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
CHEST PAIN † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CONCOMITANT DISEASE PROGRESSION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CYST † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
DEATH † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)

DISEASE PROGRESSION † 1				
# participants affected / at risk	3/101 (2.97%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
DRUG INEFFECTIVE † 1				
# participants affected / at risk	2/101 (1.98%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
DRUG INTERACTION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
GENERAL PHYSICAL HEALTH DETERIORATION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
HERNIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
HERNIA PAIN † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
INFLAMMATION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
MULTI-ORGAN FAILURE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
OEDEMA PERIPHERAL † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
PYREXIA † 1				
# participants affected / at risk	6/101 (5.94%)	4/102 (3.92%)	2/41 (4.88%)	1/40 (2.50%)
Hepatobiliary disorders				
BILE DUCT OBSTRUCTION † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
BILE DUCT STENOSIS † 1				
# participants affected / at risk	2/101 (1.98%)	5/102 (4.90%)	1/41 (2.44%)	2/40 (5.00%)
BILIARY ISCHAEMIA † 1				
# participants affected / at risk	2/101 (1.98%)	4/102 (3.92%)	2/41 (4.88%)	2/40 (5.00%)
BILIARY TRACT DISORDER † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
BILOMA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CHOLANGITIS † 1				
# participants affected / at risk	4/101 (3.96%)	10/102 (9.80%)	1/41 (2.44%)	3/40 (7.50%)
CHOLELITHIASIS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
CHOLESTASIS † 1				
# participants affected / at risk	5/101 (4.95%)	2/102 (1.96%)	0/41 (0.00%)	0/40 (0.00%)
HEPATIC ARTERY OCCLUSION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HEPATIC CIRRHOSIS † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HEPATIC FAILURE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HEPATIC HAEMORRHAGE † 1				

# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
HEPATIC LESION † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HEPATIC STEATOSIS † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HEPATIC VEIN THROMBOSIS † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
HEPATITIS † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
HEPATORENAL SYNDROME † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HEPATOTOXICITY † [1]				
# participants affected / at risk	2/101 (1.98%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
NON-ALCOHOLIC STEATOHEPATITIS † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
PORTAL VEIN THROMBOSIS † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
Immune system disorders				
HYPERSENSITIVITY † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
LIVER TRANSPLANT REJECTION † [1]				
# participants affected / at risk	4/101 (3.96%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
TRANSPLANT REJECTION † [1]				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
Infections and infestations				
ABDOMINAL ABSCESS † [1]				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
ASPERGILLOSIS † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
BILIARY SEPSIS † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
BRAIN ABSCESS † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
BRONCHITIS † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
BRONCHOPNEUMONIA † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
BRONCHOPULMONARY ASPERGILLOSIS † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
CELLULITIS † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CELLULITIS ORBITAL † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
CEREBRAL TOXOPLASMOSIS † [1]				

# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CLOSTRIDIAL INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CLOSTRIDIUM COLITIS † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
CLOSTRIDIUM DIFFICILE COLITIS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CYTOMEGALOVIRUS COLITIS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CYTOMEGALOVIRUS INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	5/102 (4.90%)	1/41 (2.44%)	0/40 (0.00%)
DEVICE RELATED INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
DIVERTICULITIS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
ENDOCARDITIS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
ENTEROCOCCAL INFECTION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
ENTEROCOCCAL SEPSIS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
ERYSIPELAS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
ESCHERICHIA URINARY TRACT INFECTION † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
GASTROENTERITIS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	1/41 (2.44%)	2/40 (5.00%)
GASTROENTERITIS NOROVIRUS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
GASTROINTESTINAL INFECTION † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
HAEMATOMA INFECTION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
HEPATITIS C † 1				
# participants affected / at risk	3/101 (2.97%)	3/102 (2.94%)	0/41 (0.00%)	1/40 (2.50%)
HERPES ZOSTER † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
INCISIONAL HERNIA GANGRENOUS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	2/41 (4.88%)	2/40 (5.00%)
LIVER ABSCESS † 1				
# participants affected / at risk	3/101 (2.97%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
OESOPHAGEAL CANDIDIASIS † 1				

# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
PANCREATITIS BACTERIAL † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PERIHEPATIC ABSCESS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PERITONEAL ABSCESS † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PERITONITIS BACTERIAL † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
PNEUMOCYSTIS JIROVECI PNEUMONIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
PNEUMONIA † 1				
# participants affected / at risk	5/101 (4.95%)	3/102 (2.94%)	1/41 (2.44%)	2/40 (5.00%)
PNEUMONIA CYTOMEGALOVIRAL † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
PNEUMONIA PRIMARY ATYPICAL † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
RESPIRATORY TRACT INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
SEPSIS † 1				
# participants affected / at risk	2/101 (1.98%)	2/102 (1.96%)	1/41 (2.44%)	0/40 (0.00%)
SEPTIC SHOCK † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
SMALL INTESTINE GANGRENE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
STENOTROPHOMONAS INFECTION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
TONSILLITIS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
URINARY TRACT INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
WOUND INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
Injury, poisoning and procedural complications				
ANASTOMOTIC STENOSIS † 1				
# participants affected / at risk	1/101 (0.99%)	2/102 (1.96%)	0/41 (0.00%)	0/40 (0.00%)
ANIMAL BITE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
BILIARY ANASTOMOSIS COMPLICATION † 1				
# participants affected / at risk	4/101 (3.96%)	3/102 (2.94%)	0/41 (0.00%)	0/40 (0.00%)
FALL † 1				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	3/41 (7.32%)	1/40 (2.50%)
FIBULA FRACTURE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)

FOOT FRACTURE † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
INCISIONAL HERNIA † [1]				
# participants affected / at risk	8/101 (7.92%)	5/102 (4.90%)	7/41 (17.07%)	5/40 (12.50%)
INCISIONAL HERNIA, OBSTRUCTIVE † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
LIVER GRAFT LOSS † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
LUMBAR VERTEBRAL FRACTURE † [1]				
# participants affected / at risk	0/101 (0.00%)	3/102 (2.94%)	0/41 (0.00%)	0/40 (0.00%)
POST PROCEDURAL HAEMORRHAGE † [1]				
# participants affected / at risk	2/101 (1.98%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PROCEDURAL COMPLICATION † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
RADIUS FRACTURE † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
RIB FRACTURE † [1]				
# participants affected / at risk	2/101 (1.98%)	0/102 (0.00%)	2/41 (4.88%)	0/40 (0.00%)
THORACIC VERTEBRAL FRACTURE † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
TIBIA FRACTURE † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	2/41 (4.88%)	0/40 (0.00%)
TRANSPLANT FAILURE † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
WOUND COMPLICATION † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
WRIST FRACTURE † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
Investigations				
ALANINE AMINOTRANSFERASE INCREASED † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
ASPARTATE AMINOTRANSFERASE INCREASED † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
BLOOD ALKALINE PHOSPHATASE INCREASED † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
BLOOD CREATININE INCREASED † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
C-REACTIVE PROTEIN INCREASED † [1]				
# participants affected / at risk	2/101 (1.98%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
CYTOMEGALOVIRUS TEST POSITIVE † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
GAMMA-GLUTAMYLTRANSFERASE INCREASED † [1]				
# participants affected / at risk	2/101 (1.98%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
HAEMOGLOBIN DECREASED † [1]				

# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
HEPATIC ENZYME INCREASED † 1				
# participants affected / at risk	14/101 (13.86%)	9/102 (8.82%)	1/41 (2.44%)	1/40 (2.50%)
LIVER FUNCTION TEST ABNORMAL † 1				
# participants affected / at risk	3/101 (2.97%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
TRANSAMINASES INCREASED † 1				
# participants affected / at risk	4/101 (3.96%)	3/102 (2.94%)	1/41 (2.44%)	1/40 (2.50%)
Metabolism and nutrition disorders				
DIABETES MELLITUS † 1				
# participants affected / at risk	0/101 (0.00%)	2/102 (1.96%)	0/41 (0.00%)	0/40 (0.00%)
ELECTROLYTE IMBALANCE † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
HYPERCHOLESTEROLAEMIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
HYPERKALAEMIA † 1				
# participants affected / at risk	0/101 (0.00%)	3/102 (2.94%)	0/41 (0.00%)	0/40 (0.00%)
HYPOGLYCAEMIA † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
HYPONATRAEMIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
HYPOVITAMINOSIS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
Musculoskeletal and connective tissue disorders				
ARTHRALGIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
ARTHROPATHY † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
BACK PAIN † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
INTERVERTEBRAL DISC PROTRUSION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	1/40 (2.50%)
OSTEOARTHRITIS † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
OSTEOPENIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
OSTEOPOROTIC FRACTURE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
ROTATOR CUFF SYNDROME † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
ADENOCARCINOMA † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
BASAL CELL CARCINOMA † 1				

# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
BLADDER TRANSITIONAL CELL CARCINOMA † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
EPSTEIN-BARR VIRUS ASSOCIATED LYMPHOPROLIFERATIVE DISORDER † 1				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
GASTRIC CANCER † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
HEPATIC NEOPLASM MALIGNANT RECURRENT † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
HEPATOCELLULAR CARCINOMA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	2/41 (4.88%)	1/40 (2.50%)
LUNG ADENOCARCINOMA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
METASTASES TO BONE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
METASTASES TO LUNG † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	1/41 (2.44%)	0/40 (0.00%)
METASTASES TO LYMPH NODES † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
METASTASES TO PERITONEUM † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
PARANEOPLASTIC SYNDROME † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
PROSTATE CANCER † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
PROSTATE CANCER METASTATIC † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
RECTAL ADENOCARCINOMA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
Nervous system disorders				
APHASIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
CAROTID ARTERY STENOSIS † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
CEREBRAL HAEMORRHAGE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
CEREBRAL INFARCTION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
CEREBRAL ISCHAEMIA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
CEREBROVASCULAR ACCIDENT † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
DIZZINESS † 1				

# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
ENCEPHALOPATHY † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
EPILEPSY † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
GRAND MAL CONVULSION † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
HEMIPARESIS † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
LACUNAR INFARCTION † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
LETHARGY † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
LOSS OF CONSCIOUSNESS † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
MIGRAINE † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
NEUROPATHY PERIPHERAL † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
NEUROTOXICITY † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PARAESTHESIA † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
POLYNEUROPATHY † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
RADICULAR SYNDROME † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
SOMNOLENCE † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
SYNCOPE † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
TRANSIENT ISCHAEMIC ATTACK † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
Psychiatric disorders				
ALCOHOLISM † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
DEPRESSION † [1]				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
DISORIENTATION † [1]				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
PSYCHOTIC DISORDER DUE TO A GENERAL MEDICAL CONDITION † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
SUICIDE ATTEMPT † [1]				

# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
Renal and urinary disorders				
HAEMATURIA † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
RENAL FAILURE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
RENAL FAILURE ACUTE † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
RENAL IMPAIRMENT † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
RENAL INJURY † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
Reproductive system and breast disorders				
MENORRHAGIA † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
OVARIAN CYST † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
SPERMATOCELE † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
TESTICULAR SWELLING † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
Respiratory, thoracic and mediastinal disorders				
COUGH † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
DYSPNOEA † 1				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
DYSPNOEA EXERTIONAL † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	1/41 (2.44%)	0/40 (0.00%)
LUNG INFILTRATION † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
PLEURAL EFFUSION † 1				
# participants affected / at risk	1/101 (0.99%)	2/102 (1.96%)	0/41 (0.00%)	1/40 (2.50%)
PNEUMONIA ASPIRATION † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	1/40 (2.50%)
PNEUMONITIS † 1				
# participants affected / at risk	1/101 (0.99%)	0/102 (0.00%)	0/41 (0.00%)	0/40 (0.00%)
PULMONARY EMBOLISM † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	1/40 (2.50%)
RESPIRATORY FAILURE † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
VOCAL CORD POLYP † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	0/41 (0.00%)	0/40 (0.00%)
Skin and subcutaneous tissue disorders				
ANGIOEDEMA † 1				

# participants affected / at risk	**0/101 (0.00%)**	**0/102 (0.00%)**	**1/41 (2.44%)**	**0/40 (0.00%)**
ERYTHEMA † 1				
# participants affected / at risk	**1/101 (0.99%)**	**0/102 (0.00%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
PRURITUS † 1				
# participants affected / at risk	**1/101 (0.99%)**	**1/102 (0.98%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
SCAR † 1				
# participants affected / at risk	**0/101 (0.00%)**	**1/102 (0.98%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
TOXIC SKIN ERUPTION † 1				
# participants affected / at risk	**1/101 (0.99%)**	**0/102 (0.00%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
Vascular disorders				
CIRCULATORY COLLAPSE † 1				
# participants affected / at risk	**0/101 (0.00%)**	**1/102 (0.98%)**	**1/41 (2.44%)**	**0/40 (0.00%)**
DEEP VEIN THROMBOSIS † 1				
# participants affected / at risk	**0/101 (0.00%)**	**0/102 (0.00%)**	**1/41 (2.44%)**	**0/40 (0.00%)**
HYPERTENSIVE CRISIS † 1				
# participants affected / at risk	**1/101 (0.99%)**	**1/102 (0.98%)**	**0/41 (0.00%)**	**1/40 (2.50%)**
SHOCK HAEMORRHAGIC † 1				
# participants affected / at risk	**1/101 (0.99%)**	**0/102 (0.00%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
STEAL SYNDROME † 1				
# participants affected / at risk	**1/101 (0.99%)**	**0/102 (0.00%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
VENA CAVA THROMBOSIS † 1				
# participants affected / at risk	**0/101 (0.00%)**	**1/102 (0.98%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
VENOUS STENOSIS † 1				
# participants affected / at risk	**0/101 (0.00%)**	**1/102 (0.98%)**	**0/41 (0.00%)**	**0/40 (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
Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Calcineurin Inhibitor (CNI)	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional steroids according to local best practice
Extension Period - Everolimus	Basiliximab plus everolimus-based immunosuppressive regimen following the reduction and cessation of initial CNI regimen plus optional steroids according to local best practice
Extension Period - CNI	Basiliximab plus CNI-based immunosuppressive regimen according to local best practice plus optional

	steroids according to local best practice

Other Adverse Events

	Everolimus	Calcineurin Inhibitor (CNI)	Extension Period - Everolimus	Extension Period - CNI
Total, other (not including serious) adverse events				
# participants affected / at risk	**92/101 (91.09%)**	**87/102 (85.29%)**	**39/41 (95.12%)**	**38/40 (95.00%)**
Blood and lymphatic system disorders				
ANAEMIA † 1				
# participants affected / at risk	**17/101 (16.83%)**	**10/102 (9.80%)**	**4/41 (9.76%)**	**1/40 (2.50%)**
LEUKOPENIA † 1				
# participants affected / at risk	**19/101 (18.81%)**	**10/102 (9.80%)**	**1/41 (2.44%)**	**3/40 (7.50%)**
THROMBOCYTOPENIA † 1				
# participants affected / at risk	**8/101 (7.92%)**	**7/102 (6.86%)**	**2/41 (4.88%)**	**4/40 (10.00%)**
Cardiac disorders				
TACHYCARDIA † 1				
# participants affected / at risk	**6/101 (5.94%)**	**2/102 (1.96%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
Endocrine disorders				
HYPOTHYROIDISM † 1				
# participants affected / at risk	**0/101 (0.00%)**	**0/102 (0.00%)**	**1/41 (2.44%)**	**2/40 (5.00%)**
Gastrointestinal disorders				
ABDOMINAL DISCOMFORT † 1				
# participants affected / at risk	**2/101 (1.98%)**	**1/102 (0.98%)**	**0/41 (0.00%)**	**2/40 (5.00%)**
ABDOMINAL PAIN † 1				
# participants affected / at risk	**11/101 (10.89%)**	**10/102 (9.80%)**	**4/41 (9.76%)**	**2/40 (5.00%)**
ABDOMINAL PAIN UPPER † 1				
# participants affected / at risk	**6/101 (5.94%)**	**6/102 (5.88%)**	**5/41 (12.20%)**	**2/40 (5.00%)**
APHTHOUS STOMATITIS † 1				
# participants affected / at risk	**8/101 (7.92%)**	**1/102 (0.98%)**	**2/41 (4.88%)**	**0/40 (0.00%)**
ASCITES † 1				
# participants affected / at risk	**1/101 (0.99%)**	**8/102 (7.84%)**	**1/41 (2.44%)**	**2/40 (5.00%)**
CONSTIPATION † 1				
# participants affected / at risk	**9/101 (8.91%)**	**11/102 (10.78%)**	**1/41 (2.44%)**	**3/40 (7.50%)**
DIARRHOEA † 1				
# participants affected / at risk	**27/101 (26.73%)**	**13/102 (12.75%)**	**10/41 (24.39%)**	**4/40 (10.00%)**
FLATULENCE † 1				
# participants affected / at risk	**7/101 (6.93%)**	**10/102 (9.80%)**	**5/41 (12.20%)**	**2/40 (5.00%)**
GASTROOESOPHAGEAL REFLUX DISEASE † 1				
# participants affected / at risk	**2/101 (1.98%)**	**1/102 (0.98%)**	**4/41 (9.76%)**	**2/40 (5.00%)**
NAUSEA † 1				
	12/101 (11.88%)			

# participants affected / at risk		16/102 (15.69%)	5/41 (12.20%)	3/40 (7.50%)
VOMITING † 1				
# participants affected / at risk	6/101 (5.94%)	12/102 (11.76%)	3/41 (7.32%)	0/40 (0.00%)
General disorders				
FATIGUE † 1				
# participants affected / at risk	5/101 (4.95%)	6/102 (5.88%)	2/41 (4.88%)	3/40 (7.50%)
IMPAIRED HEALING † 1				
# participants affected / at risk	0/101 (0.00%)	1/102 (0.98%)	2/41 (4.88%)	2/40 (5.00%)
OEDEMA † 1				
# participants affected / at risk	5/101 (4.95%)	6/102 (5.88%)	0/41 (0.00%)	0/40 (0.00%)
OEDEMA PERIPHERAL † 1				
# participants affected / at risk	15/101 (14.85%)	9/102 (8.82%)	13/41 (31.71%)	3/40 (7.50%)
PYREXIA † 1				
# participants affected / at risk	14/101 (13.86%)	12/102 (11.76%)	4/41 (9.76%)	3/40 (7.50%)
Hepatobiliary disorders				
CHOLANGITIS † 1				
# participants affected / at risk	6/101 (5.94%)	5/102 (4.90%)	1/41 (2.44%)	1/40 (2.50%)
CHOLESTASIS † 1				
# participants affected / at risk	9/101 (8.91%)	4/102 (3.92%)	2/41 (4.88%)	1/40 (2.50%)
HEPATIC STEATOSIS † 1				
# participants affected / at risk	2/101 (1.98%)	4/102 (3.92%)	6/41 (14.63%)	5/40 (12.50%)
Infections and infestations				
BRONCHITIS † 1				
# participants affected / at risk	2/101 (1.98%)	1/102 (0.98%)	6/41 (14.63%)	6/40 (15.00%)
CYTOMEGALOVIRUS INFECTION † 1				
# participants affected / at risk	7/101 (6.93%)	7/102 (6.86%)	1/41 (2.44%)	0/40 (0.00%)
NASOPHARYNGITIS † 1				
# participants affected / at risk	15/101 (14.85%)	15/102 (14.71%)	9/41 (21.95%)	8/40 (20.00%)
PERIODONTITIS † 1				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	5/41 (12.20%)	2/40 (5.00%)
SINUSITIS † 1				
# participants affected / at risk	6/101 (5.94%)	1/102 (0.98%)	4/41 (9.76%)	1/40 (2.50%)
UPPER RESPIRATORY TRACT INFECTION † 1				
# participants affected / at risk	1/101 (0.99%)	2/102 (1.96%)	4/41 (9.76%)	1/40 (2.50%)
URINARY TRACT INFECTION † 1				
# participants affected / at risk	16/101 (15.84%)	13/102 (12.75%)	6/41 (14.63%)	4/40 (10.00%)
WOUND INFECTION † 1				
# participants affected / at risk	7/101 (6.93%)	2/102 (1.96%)	2/41 (4.88%)	0/40 (0.00%)
Injury, poisoning and procedural complications				
INCISIONAL HERNIA † 1				
# participants affected / at risk	4/101 (3.96%)	5/102 (4.90%)	7/41 (17.07%)	2/40 (5.00%)

PROCEDURAL PAIN † [1]				
# participants affected / at risk	4/101 (3.96%)	8/102 (7.84%)	3/41 (7.32%)	1/40 (2.50%)
Investigations				
C-REACTIVE PROTEIN INCREASED † [1]				
# participants affected / at risk	8/101 (7.92%)	2/102 (1.96%)	2/41 (4.88%)	1/40 (2.50%)
HEPATIC ENZYME INCREASED † [1]				
# participants affected / at risk	14/101 (13.86%)	3/102 (2.94%)	0/41 (0.00%)	4/40 (10.00%)
TRANSAMINASES INCREASED † [1]				
# participants affected / at risk	8/101 (7.92%)	6/102 (5.88%)	4/41 (9.76%)	1/40 (2.50%)
WEIGHT DECREASED † [1]				
# participants affected / at risk	1/101 (0.99%)	1/102 (0.98%)	1/41 (2.44%)	2/40 (5.00%)
Metabolism and nutrition disorders				
DIABETES MELLITUS † [1]				
# participants affected / at risk	4/101 (3.96%)	6/102 (5.88%)	5/41 (12.20%)	2/40 (5.00%)
HYPERCHOLESTEROLAEMIA † [1]				
# participants affected / at risk	22/101 (21.78%)	11/102 (10.78%)	4/41 (9.76%)	2/40 (5.00%)
HYPERKALAEMIA † [1]				
# participants affected / at risk	1/101 (0.99%)	7/102 (6.86%)	0/41 (0.00%)	2/40 (5.00%)
HYPERLIPIDAEMIA † [1]				
# participants affected / at risk	12/101 (11.88%)	2/102 (1.96%)	1/41 (2.44%)	0/40 (0.00%)
HYPERTRIGLYCERIDAEMIA † [1]				
# participants affected / at risk	6/101 (5.94%)	3/102 (2.94%)	2/41 (4.88%)	1/40 (2.50%)
HYPERURICAEMIA † [1]				
# participants affected / at risk	5/101 (4.95%)	7/102 (6.86%)	2/41 (4.88%)	3/40 (7.50%)
HYPOKALAEMIA † [1]				
# participants affected / at risk	13/101 (12.87%)	9/102 (8.82%)	3/41 (7.32%)	1/40 (2.50%)
OBESITY † [1]				
# participants affected / at risk	0/101 (0.00%)	0/102 (0.00%)	0/41 (0.00%)	2/40 (5.00%)
Musculoskeletal and connective tissue disorders				
ARTHRALGIA † [1]				
# participants affected / at risk	7/101 (6.93%)	10/102 (9.80%)	3/41 (7.32%)	2/40 (5.00%)
BACK PAIN † [1]				
# participants affected / at risk	12/101 (11.88%)	13/102 (12.75%)	9/41 (21.95%)	1/40 (2.50%)
MUSCLE SPASMS † [1]				
# participants affected / at risk	4/101 (3.96%)	7/102 (6.86%)	1/41 (2.44%)	1/40 (2.50%)
OSTEOPENIA † [1]				
# participants affected / at risk	0/101 (0.00%)	3/102 (2.94%)	2/41 (4.88%)	2/40 (5.00%)
OSTEOPOROSIS † [1]				
# participants affected / at risk	2/101 (1.98%)	4/102 (3.92%)	6/41 (14.63%)	1/40 (2.50%)
PAIN IN EXTREMITY † [1]				
# participants affected / at risk	5/101 (4.95%)	6/102 (5.88%)	7/41 (17.07%)	0/40 (0.00%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
MELANOCYTIC NAEVUS † 1				
# participants affected / at risk	**1/101 (0.99%)**	**0/102 (0.00%)**	**0/41 (0.00%)**	**2/40 (5.00%)**
Nervous system disorders				
HEADACHE † 1				
# participants affected / at risk	**20/101 (19.80%)**	**10/102 (9.80%)**	**3/41 (7.32%)**	**1/40 (2.50%)**
PARAESTHESIA † 1				
# participants affected / at risk	**4/101 (3.96%)**	**4/102 (3.92%)**	**3/41 (7.32%)**	**1/40 (2.50%)**
TREMOR † 1				
# participants affected / at risk	**6/101 (5.94%)**	**9/102 (8.82%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
Psychiatric disorders				
DEPRESSION † 1				
# participants affected / at risk	**3/101 (2.97%)**	**6/102 (5.88%)**	**2/41 (4.88%)**	**7/40 (17.50%)**
INSOMNIA † 1				
# participants affected / at risk	**8/101 (7.92%)**	**9/102 (8.82%)**	**1/41 (2.44%)**	**2/40 (5.00%)**
SLEEP DISORDER † 1				
# participants affected / at risk	**4/101 (3.96%)**	**6/102 (5.88%)**	**4/41 (9.76%)**	**1/40 (2.50%)**
Renal and urinary disorders				
PROTEINURIA † 1				
# participants affected / at risk	**10/101 (9.90%)**	**2/102 (1.96%)**	**4/41 (9.76%)**	**0/40 (0.00%)**
RENAL FAILURE † 1				
# participants affected / at risk	**3/101 (2.97%)**	**7/102 (6.86%)**	**2/41 (4.88%)**	**6/40 (15.00%)**
RENAL FAILURE CHRONIC † 1				
# participants affected / at risk	**0/101 (0.00%)**	**2/102 (1.96%)**	**0/41 (0.00%)**	**2/40 (5.00%)**
URINARY INCONTINENCE † 1				
# participants affected / at risk	**0/101 (0.00%)**	**0/102 (0.00%)**	**0/41 (0.00%)**	**2/40 (5.00%)**
Reproductive system and breast disorders				
METRORRHAGIA † 1				
# participants affected / at risk	**1/101 (0.99%)**	**0/102 (0.00%)**	**0/41 (0.00%)**	**2/40 (5.00%)**
Respiratory, thoracic and mediastinal disorders				
COUGH † 1				
# participants affected / at risk	**6/101 (5.94%)**	**1/102 (0.98%)**	**4/41 (9.76%)**	**2/40 (5.00%)**
DYSPNOEA † 1				
# participants affected / at risk	**6/101 (5.94%)**	**5/102 (4.90%)**	**0/41 (0.00%)**	**0/40 (0.00%)**
PLEURAL EFFUSION † 1				
# participants affected / at risk	**9/101 (8.91%)**	**8/102 (7.84%)**	**1/41 (2.44%)**	**0/40 (0.00%)**
Skin and subcutaneous tissue disorders				
PRURITUS † 1				
# participants affected / at risk	**19/101 (18.81%)**	**11/102 (10.78%)**	**5/41 (12.20%)**	**4/40 (10.00%)**
RASH † 1				

# participants affected / at risk	**5/101 (4.95%)**	**1/102 (0.98%)**	**1/41 (2.44%)**	**3/40 (7.50%)**
Vascular disorders				
HYPERTENSION † 1				
# participants affected / at risk	**20/101 (19.80%)**	**14/102 (13.73%)**	**6/41 (14.63%)**	**6/40 (15.00%)**

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

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
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: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00378014 History of Changes
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Study First Received:	September 15, 2006
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Last Updated:	January 19, 2015
Health Authority:	United States: Food and Drug Administration Belgium: Federal Agency for Medicines and Health Products, FAMHP