Trial record **1 of 1** for: COLO400A2430
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Sustained Virological Response (SVR) to Antiviral Treatment of Liver Transplant Recipients With Recurrent Hepatitis C (SUSTAIN)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00938860

First received: July 13, 2009
Last updated: May 5, 2015
Last verified: May 2015
History of Changes

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Results First Received: April 25, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Hepatitis C Liver Transplantation
Interventions:	Drug: cyclosporin (Neoral) Drug: tacrolimus (Prograf)

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
This was an 80 week multicenter randomized, open label, controlled study in adult HCVpositive maintenance liver transplant recipients. Patients were randomized at a 1.3:1 ratio to CsA and tacrolimus. Patients randomized to tacrolimus were maintained on treatment with tacrolimus, patients randomized to CsA were converted from tacrolimus to CsA

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Participant Flow: Overall Study

	Neoral	Tacrolimus
STARTED	50 [1]	42
Efficacy Population	40	41
COMPLETED	25	25
NOT COMPLETED	25	17
Adverse Event	2	1
Abnormal laboratory values	2	2
Withdrawal by Subject	11	8
Lost to Follow-up	4	4
Administration problems	2	0
Death	1	1
Protocol Violation	3	1

[1] Intent-to-Treat (ITT) population. ITT population consisted of all randomized patients

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.
Intent-to-Treat (ITT) population: The ITT population consisted of all randomized patients.

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges
Total	Total of all reporting groups

Baseline Measures

	Neoral	Tacrolimus	Total
Number of Participants [units: participants]	**50**	**42**	**92**
Age [units: Years] Mean (Standard Deviation)	**54.2 (6.30)**	**55.0 (6.84)**	**54.6 (6.53)**
Gender [units: Participants]			
Female	**9**	**8**	**17**
Male	**41**	**34**	**75**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Sustained Virological Response (SVR) Following Treatment of Hepatitis C Virus (HCV) Infection With Peg-IFN and Ribavirin in Liver Transplanted Recipients on Maintenance Therapy With Neoral or Tacrolimus [Time Frame: Week 24]

Measure Type	Primary
Measure Title	Number of Participants Sustained Virological Response (SVR) Following Treatment of Hepatitis C Virus (HCV) Infection With Peg-IFN and Ribavirin in Liver Transplanted Recipients on Maintenance Therapy With Neoral or Tacrolimus
Measure Description	The achievement of SVR, defined as HCV RNA below limit of detection at the end of AV treatment, 24 weeks after end of AV treatment (W24 post). A dichotomous variable (SVR achieved: Yes/No) was computed. A patient was classified as non-responder (SVR not achieved) if HCV RNA was detectable at the completion of antiviral treatment, at W24post, or at any time between W24 and completion of antiviral treatment. The HCV RNA detection limit was <15 IU/ml (<1.18 log IU/ml)
Time Frame	Week 24
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 efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**20**	**23**
Number of Participants Sustained Virological Response (SVR) Following Treatment of Hepatitis C Virus (HCV) Infection With Peg-IFN and Ribavirin in Liver Transplanted Recipients on Maintenance Therapy With Neoral or Tacrolimus [units: Participants]	**12**	**10**

No statistical analysis provided for Number of Participants Sustained Virological Response (SVR) Following Treatment of Hepatitis C Virus (HCV) Infection With Peg-IFN and Ribavirin in Liver Transplanted Recipients on Maintenance Therapy With Neoral or Tacrolimus

2. Secondary: Number of Events of the Composite Endpoint of Biopsy Proven Acute Rejections (BPAR), Death or Graft Loss and of the Individual Components [Time Frame: Week 80]

Measure Type	Secondary
Measure Title	Number of Events of the Composite Endpoint of Biopsy Proven Acute Rejections (BPAR), Death or Graft Loss and of the Individual Components

Measure Description	Efficacy failure (biopsy proven acute rejection (BPAR), graft loss, or death
Time Frame	Week 80
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.
Intent-to-Treat (ITT) population: The ITT population consisted of all randomized patients. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**50**	**42**
Number of Events of the Composite Endpoint of Biopsy Proven Acute Rejections (BPAR), Death or Graft Loss and of the Individual Components [units: Number of events]		
BPAR, graft loss, or death	**2**	**1**
BPAR	**1**	**0**
Graft loss or death	**1**	**1**
Death	**1**	**1**

No statistical analysis provided for Number of Events of the Composite Endpoint of Biopsy Proven Acute Rejections (BPAR), Death or Graft Loss and of the Individual Components

3. Secondary: Number of Participants With Fibrosis Progression (Increase in Ishak-Knodell (IK) Score by at Least One Point From the Baseline) [Time Frame: Week 80]

Measure Type	Secondary
Measure Title	Number of Participants With Fibrosis Progression (Increase in Ishak-Knodell (IK) Score by at Least One Point From the Baseline)
Measure Description	Ishak-Knodell Score: 0=No fibrosis; 01=Fibrous expansion of some portal areas, with or without short fibrous septa; 02=Fibrous expansion of most portal areas, with or without short fibrous septa; 03=Fibrous expansion of most portal areas, with occasional portal to portal (P-P) bridging; 04=Fibrous expansion of portal areas, with marked bridging (portal to portal (P-P) as well as portal to central (P-C)); 05=Marked bridging (P-P and/or P-C) with occasional nodules (incomplete cirrhosis); 06=Cirrhosis, probable or definite, Participants showing an increase of Ishak Knodell fibrosis score by at least one level (increase of ≥1)
Time Frame	Week 80
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 efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**13**	**17**
Number of Participants With Fibrosis Progression (Increase in Ishak-Knodell (IK) Score by at Least One Point From the Baseline) [units: Participants]	**3**	**5**

No statistical analysis provided for Number of Participants With Fibrosis Progression (Increase in Ishak-Knodell (IK) Score by at Least One Point From the Baseline)

4. Secondary: Number of Participants of Rapid Viral Response (RVR) [Time Frame: Week 4]

Measure Type	Secondary
Measure Title	Number of Participants of Rapid Viral Response (RVR)
Measure Description	RVR defined as non-detectable HCV RNA 4 weeks after initiation of antiviral treatment. The HCV RNA detection limit was <15 IU/ml (<1.18 log IU/ml)
Time Frame	Week 4
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 efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	Tacrolimus
Number of Participants Analyzed [units: participants]	**36**	**38**
Number of Participants of Rapid Viral Response (RVR) [units: Participants]	**4**	**5**

No statistical analysis provided for Number of Participants of Rapid Viral Response (RVR)

5. Secondary: Number of Participants of Early Viral Response (EVR) [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Number of Participants of Early Viral Response (EVR)
Measure Description	EVR defined as non-detectable HCV RNA or a ≥2 logs reduction of HCV RNA at 12 weeks after initiation of antiviral treatment. The HCV RNA detection limit was <15 IU/ml (<1.18 log IU/ml)
Time Frame	Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	Tacrolimus
Number of Participants Analyzed [units: participants]	**31**	**36**
Number of Participants of Early Viral Response (EVR) [units: Participants]	**28**	**30**

No statistical analysis provided for Number of Participants of Early Viral Response (EVR)

6. Secondary: Number of Participants for the End of Treatment Response (ETR) [Time Frame: Week 80]

Measure Type	Secondary
Measure Title	Number of Participants for the End of Treatment Response (ETR)
Measure Description	ETR defined as non-detectable HCV RNA at the completion of AV treatment. The HCV RNA detection limit was <15

	IU/ml (<1.18 log IU/ml)
Time Frame	Week 80
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 efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**35**	**39**
Number of Participants for the End of Treatment Response (ETR) [units: Participants]	**24**	**27**

No statistical analysis provided for Number of Participants for the End of Treatment Response (ETR)

7. Secondary: Number of Participants of True Non-responder Rate [Time Frame: Week 80]

Measure Type	Secondary
Measure Title	Number of Participants of True Non-responder Rate
Measure Description	Defined as failure to achieve at least a 2 log reduction of Hepatitis C virus (HCV) RNA. The HCV RNA detection limit was <15 IU/ml (<1.18 log IU/ml)
Time Frame	Week 80
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 efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges

Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	Tacrolimus
Number of Participants Analyzed [units: participants]	**40**	**41**
Number of Participants of True Non-responder Rate [units: Participants]	**7**	**5**

No statistical analysis provided for Number of Participants of True Non-responder Rate

8. Secondary: Number of Participants for Relapse Rate [Time Frame: Week 24]

Measure Type	Secondary
Measure Title	Number of Participants for Relapse Rate
Measure Description	Defined as reappearance of detectable Hepatitis C Virus (HCV) RNA at 24 weeks after completion of antiviral treatment when HCV RNA was undetectable at the end of treatment. The HCV RNA detection limit was <15 IU/ml (<1.18 log IU/ml)
Time Frame	Week 24
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 efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	Tacrolimus
Number of Participants Analyzed [units: participants]	**23**	**21**
Number of Participants for Relapse Rate [units: Participants]	**5**	**7**

No statistical analysis provided for Number of Participants for Relapse Rate

9. Secondary: Number of Participants With Dose Reduction or Discontinuation of Antiviral (AV) Therapy Due to Poor Tolerability at Any Time During the Study for Any Reason [Time Frame: Week 80]

Measure Type	Secondary
Measure Title	Number of Participants With Dose Reduction or Discontinuation of Antiviral (AV) Therapy Due to Poor Tolerability at Any Time During the Study for Any Reason
Measure Description	Defined as number of patients with dose reduction or discontinuation of AV therapy due to poor tolerability
Time Frame	Week 80
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 efficacy population was defined as a subset of the ITT population with sufficient compliance to the protocol procedures to allow meaningful conclusions. Patients were excluded from the Efficacy population in case of: Error in treatment assignment, if the randomized study medication was not initiated, antiviral therapy was not initiated

Reporting Groups

	Description
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Measured Values

	Neoral	Tacrolimus
Number of Participants Analyzed [units: participants]	**40**	**41**
Number of Participants With Dose Reduction or Discontinuation of Antiviral (AV) Therapy Due to Poor Tolerability at Any Time During the Study for Any Reason [units: Participants]		
Neoral Antiviral treatment: Ribavirin	**25**	**0**
Neoral Antiviral treatment: Peg-IFN	**10**	**0**
Tacrolimus Antiviral treatment: Ribavirin	**0**	**23**
Tacrolimus Antiviral treatment: Peg-IFN	**0**	**11**

No statistical analysis provided for Number of Participants With Dose Reduction or Discontinuation of Antiviral (AV) Therapy Due to Poor Tolerability at Any Time During the Study for Any Reason

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges

Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges

Serious Adverse Events

	Tacrolimus	Neoral
Total, serious adverse events		
# participants affected / at risk	**17/42 (40.48%)**	**18/50 (36.00%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**5/42 (11.90%)**	**6/50 (12.00%)**
Haemolysis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Haemolytic anaemia † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Leukopenia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Pancytopenia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Angina pectoris † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Coronary artery disease † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Ventricular fibrillation † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Eye disorders		
Exophthalmos † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Gastrointestinal disorders		
Abdominal distension † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Abdominal pain † 1		
# participants affected / at risk	**1/42 (2.38%)**	**2/50 (4.00%)**
Abdominal pain upper † 1		
# participants affected / at risk	**2/42 (4.76%)**	**0/50 (0.00%)**
Anal fissure † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Ascites † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Diarrhoea † 1		
# participants affected / at risk	**2/42 (4.76%)**	**0/50 (0.00%)**

Nausea † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Pancreatitis acute † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Vomiting † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**2/50 (4.00%)**
Fatigue † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Pyrexia † 1		
# participants affected / at risk	**3/42 (7.14%)**	**2/50 (4.00%)**
Hepatobiliary disorders		
Bile duct stenosis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Bile duct stone † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Cholangitis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Cholestasis † 1		
# participants affected / at risk	**2/42 (4.76%)**	**0/50 (0.00%)**
Hepatic function abnormal † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Immune system disorders		
Liver transplant rejection † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Transplant rejection † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Infections and infestations		
Clostridium difficile colitis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Dengue fever † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Enterobacter bacteraemia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Gastroenteritis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Hepatitis C † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Pneumonia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Pyelonephritis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**

Pyoderma † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Sepsis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Septic shock † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Urinary tract infection † 1		
# participants affected / at risk	**0/42 (0.00%)**	**3/50 (6.00%)**
Urosepsis † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Injury, poisoning and procedural complications		
Biliary anastomosis complication † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Hyponatraemia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Metabolic acidosis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Musculoskeletal and connective tissue disorders		
Tenosynovitis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Nervous system disorders		
Balance disorder † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Cerebral haemorrhage † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Dementia Alzheimer's type † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Encephalopathy † 1		
# participants affected / at risk	**2/42 (4.76%)**	**1/50 (2.00%)**
Headache † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Hepatic encephalopathy † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Posterior reversible encephalopathy syndrome † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Syncope † 1		
# participants affected / at risk	**2/42 (4.76%)**	**0/50 (0.00%)**
Psychiatric disorders		
Adjustment disorder with depressed mood † 1		

# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Drug abuse † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Renal and urinary disorders		
Calculus ureteric † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Renal colic † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Renal failure † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Renal failure acute † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Renal impairment † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (0.00%)**
Reproductive system and breast disorders		
Gynaecomastia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/50 (2.00%)**
Prostatitis † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Respiratory, thoracic and mediastinal disorders		
Respiratory failure † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/50 (2.00%)**
Vascular disorders		
Shock † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/50 (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
Tacrolimus	Prograf® (tacrolimus) provided as 0.5 mg, 1 mg and 5 mg capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals. Doses were adjusted as necessary to achieve and maintain recommended C0 target ranges
Neoral	Neoral® (cyclosporine for microemulsion), available as 10 mg, 25 mg, 50 mg and 100 mg soft gelatin capsules taken on a twice daily (b.i.d) schedule at 12-hour intervals, Doses were to be adjusted as necessary to achieve and maintain recommended C0 (monitoring of trough levels) or C2 concentration 2 hours post dosing) target ranges

Other Adverse Events

	Tacrolimus	Neoral
Total, other (not including serious) adverse events		
# participants affected / at risk	**41/42 (97.62%)**	**42/50 (84.00%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**28/42 (66.67%)**	**27/50 (54.00%)**
Leukopenia † 1		
# participants affected / at risk	**9/42 (21.43%)**	**10/50 (20.00%)**
Neutropenia † 1		
# participants affected / at risk	**14/42 (33.33%)**	**6/50 (12.00%)**
Thrombocytopenia † 1		
# participants affected / at risk	**4/42 (9.52%)**	**4/50 (8.00%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**3/42 (7.14%)**	**1/50 (2.00%)**
Abdominal pain upper † 1		
# participants affected / at risk	**2/42 (4.76%)**	**4/50 (8.00%)**
Constipation † 1		
# participants affected / at risk	**2/42 (4.76%)**	**4/50 (8.00%)**
Diarrhoea † 1		
# participants affected / at risk	**11/42 (26.19%)**	**9/50 (18.00%)**
Nausea † 1		
# participants affected / at risk	**11/42 (26.19%)**	**6/50 (12.00%)**
Stomatitis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**4/50 (8.00%)**
Vomiting † 1		
# participants affected / at risk	**1/42 (2.38%)**	**3/50 (6.00%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**10/42 (23.81%)**	**7/50 (14.00%)**
Chills † 1		
# participants affected / at risk	**3/42 (7.14%)**	**2/50 (4.00%)**
Fatigue † 1		
# participants affected / at risk	**13/42 (30.95%)**	**12/50 (24.00%)**
Influenza like illness † 1		
# participants affected / at risk	**7/42 (16.67%)**	**3/50 (6.00%)**
Irritability † 1		
# participants affected / at risk	**6/42 (14.29%)**	**0/50 (0.00%)**
Oedema peripheral † 1		
# participants affected / at risk	**2/42 (4.76%)**	**5/50 (10.00%)**
Pain † 1		
# participants affected / at risk	**0/42 (0.00%)**	**3/50 (6.00%)**
Pyrexia † 1		

# participants affected / at risk	5/42 (11.90%)	8/50 (16.00%)
Infections and infestations		
Urinary tract infection † 1		
# participants affected / at risk	3/42 (7.14%)	2/50 (4.00%)
Investigations		
Haemoglobin decreased † 1		
# participants affected / at risk	4/42 (9.52%)	0/50 (0.00%)
Neutrophil count decreased † 1		
# participants affected / at risk	3/42 (7.14%)	1/50 (2.00%)
Weight decreased † 1		
# participants affected / at risk	4/42 (9.52%)	1/50 (2.00%)
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	5/42 (11.90%)	5/50 (10.00%)
Hyperkalaemia † 1		
# participants affected / at risk	2/42 (4.76%)	4/50 (8.00%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	3/42 (7.14%)	3/50 (6.00%)
Back pain † 1		
# participants affected / at risk	3/42 (7.14%)	1/50 (2.00%)
Muscle spasms † 1		
# participants affected / at risk	7/42 (16.67%)	1/50 (2.00%)
Myalgia † 1		
# participants affected / at risk	4/42 (9.52%)	1/50 (2.00%)
Pain in extremity † 1		
# participants affected / at risk	3/42 (7.14%)	3/50 (6.00%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	8/42 (19.05%)	4/50 (8.00%)
Headache † 1		
# participants affected / at risk	7/42 (16.67%)	8/50 (16.00%)
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	2/42 (4.76%)	3/50 (6.00%)
Depression † 1		
# participants affected / at risk	4/42 (9.52%)	7/50 (14.00%)
Insomnia † 1		
# participants affected / at risk	6/42 (14.29%)	6/50 (12.00%)
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	4/42 (9.52%)	6/50 (12.00%)
Dyspnoea † 1		

# participants affected / at risk	**8/42 (19.05%)**	**5/50 (10.00%)**
Skin and subcutaneous tissue disorders		
Alopecia † 1		
# participants affected / at risk	**3/42 (7.14%)**	**0/50 (0.00%)**
Eczema † 1		
# participants affected / at risk	**2/42 (4.76%)**	**3/50 (6.00%)**
Pruritus † 1		
# participants affected / at risk	**6/42 (14.29%)**	**6/50 (12.00%)**
Pruritus generalised † 1		
# participants affected / at risk	**4/42 (9.52%)**	**1/50 (2.00%)**
Rash † 1		
# participants affected / at risk	**3/42 (7.14%)**	**1/50 (2.00%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**4/42 (9.52%)**	**9/50 (18.00%)**

† 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
e-mail: trialandresults.registries@novartis.com

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00938860 History of Changes
Other Study ID Numbers:	**COLO400A2430** 2009-010806-12
Study First Received:	July 13, 2009
Results First Received:	April 25, 2014
Last Updated:	May 5, 2015
Health Authority:	United States: Food and Drug Administration Argentina: Ministry of Health Austria: Federal Office for Safety in Health Care Belgium: Federal Agency for Medicinal Products and Health Products Brazil: Ministry of Health Canada: Health Canada Colombia: INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos France: Ministry of Health Germany: Ministry of Health Hungary: National Institute of Pharmacy Italy: Ministry of Health Korea: Food and Drug Administration Romania: Ministry of Public Health Russia: Ministry of Health of the Russian Federation Spain: Ministry of Health Switzerland: Swissmedic United Kingdom: Medicines and Healthcare Products Regulatory Agency