ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: COLO400A2426

Previous Study | Return to List | Next Study

Liver Fibrosis in Patients Transplanted for Hepatitis C Receiving Either Cyclosporine Microemulsion or Tacrolimus

This study has been terminated.

(Study was prematurely terminated due to poor recruitment.)

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00260208

First received: November 30, 2005
Last updated: December 2, 2011
Last verified: December 2011
History of Changes

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

Results First Received: September 14, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Prevention
Conditions:	Liver Transplant Hepatitis C
Interventions:	Drug: Cyclosporine A Drug: Tacrolimus

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
361 patients were randomized, 185 to the cyclosporin A arm and 176 to tacrolimus. Five patients (1 cyclosporine A, 4 tacrolimus) did not receive any dose of study medication and were therefore excluded from the safety population.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily

	(b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Participant Flow: Overall Study

	Cyclosporin A	Tacrolimus
STARTED	184 [1]	172
Intent to Treat (ITT) Population	182	169
Modified ITT	101	96
COMPLETED	137	138
NOT COMPLETED	47	34
Subject withdrew consent	11	7
Lost to Follow-up	6	1
Death	12	10
Missing	18	16

[1] "Started" indicates safety population.

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
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.
Total	Total of all reporting groups

Baseline Measures

	Cyclosporin A	Tacrolimus	Total
Number of Participants [units: participants]	182	169	351
Age [1] [units: years] Mean (Standard Deviation)	54.4 (6.9)	54.4 (7.1)	54.4 (7.0)
Age, Customized [units: Participants]			
< 65 years	163	154	317
≥ 65 years	19	15	34

Gender [units: participants]			
Female	57	48	105
Male	125	121	246

[1] Baseline measurements were based on intent-to-treat population which included all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant [Time Frame: 1 year post-transplant]

Measure Type	Primary
Measure Title	Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant
Measure Description	Assessment of hepatic fibrosis was performed with liver biopsies at Day 1, Month 6, 12 and 24, read centrally by two independent pathologists blinded to treatment arm and time of biopsy. Ishak-Knodell score was used to stage liver disease; 0= None; 1= Portal fibrosis (some); 2= Portal fibrosis (most); 3= Bridging fibrosis (few); 4= Bridging fibrosis (many); 5 = Incomplete cirrhosis; 6 = Cirrhosis. Higher score indicates greater fibrosis. Logistic regression on the presence of IK>=2 was applied based on central biopsy readings only.
Time Frame	1 year post-transplant
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The modified intent-to-treat population (mITT) included patients treated with study drug at least up to 30 days before Month 12 visit and a liver biopsy had to be performed at this visit. Also included were patients with an earlier biopsy that showed an Ishak-Knodell fibrosis score ≥2 and treated at least up to 30 days before that biopsy was taken.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	Tacrolimus
Number of Participants Analyzed [units: participants]	**88**	**77**
Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant [units: Participants]	**63**	**52**

No statistical analysis provided for Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant

2. Secondary: Number of Participants With Combined Endpoint of Death or Graft Loss or Fibrosis Score (FS) ≥ 2 [Time Frame: 1 year post-transplant]

Measure Type	Secondary
Measure Title	Number of Participants With Combined Endpoint of Death or Graft Loss or Fibrosis Score (FS) ≥ 2
Measure Description	The number of participants with combined end point of death or graft loss or presented with a Ishak-Knodell fibrosis score (FS) ≥2 was calculated. Graft loss was considered to have occurred when allograft was presumed to be lost if a patient had liver retransplant or died. Assessment of hepatic fibrosis was performed with liver biopsies read centrally. Ishak-Knodell FS was used to stage liver disease; 0=none; 1=portal fibrosis (some); 2=portal fibrosis (most); 3=bridging fibrosis (few); 4=bridging fibrosis (many); 5=Incomplete cirrhosis; 6=cirrhosis. Higher score indicates greater fibrosis.
Time Frame	1 year post-transplant
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.
Intent-to-treat (ITT) population: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**182**	**169**
Number of Participants With Combined Endpoint of Death or Graft Loss or Fibrosis Score (FS) ≥ 2 [units: Participants]	**77**	**71**

No statistical analysis provided for Number of Participants With Combined Endpoint of Death or Graft Loss or Fibrosis Score (FS) ≥ 2

3. Secondary: Number of Participants With Fibrosing Cholestatic Hepatitis [Time Frame: 1 year post-transplantation]

Measure Type	Secondary
Measure Title	Number of Participants With Fibrosing Cholestatic Hepatitis

Measure Description	Fibrosing cholestatic hepatitis (FCH) is characterized by progressive jaundice with a rapid decline in liver function leading to liver failure, most often associated with markedly elevated viral levels detected in the bloodstream (e.g. more than 20 times pre-liver transplantation levels) and in the liver tissue as well. The presence of FCH was reported based on the diagnosis given by the investigator.
Time Frame	1 year post-transplantation
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 population: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**182**	**169**
Number of Participants With Fibrosing Cholestatic Hepatitis [units: Participants]	**9**	**6**

No statistical analysis provided for Number of Participants With Fibrosing Cholestatic Hepatitis

4. Secondary: Number of Participants With Death, Graft Loss, Death or Graft Loss, Graft Loss With Re-transplantation [Time Frame: 1 year post-transplant]

Measure Type	Secondary
Measure Title	Number of Participants With Death, Graft Loss, Death or Graft Loss, Graft Loss With Re-transplantation
Measure Description	Graft loss was considered to have occurred when allograft was presumed to be lost if a patient had a liver re-transplant or died.
Time Frame	1 year post-transplant
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.
Intent-to-treat (ITT) population: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	Tacrolimus
Number of Participants Analyzed [units: participants]	**182**	**169**
Number of Participants With Death, Graft Loss, Death or Graft Loss, Graft Loss With Re-transplantation [units: Participants]		
Death	**15**	**15**
Graft loss	**8**	**13**
Death or Graft loss	**19**	**23**
Graft loss with re-transplantation	**3**	**8**

No statistical analysis provided for Number of Participants With Death, Graft Loss, Death or Graft Loss, Graft Loss With Re-transplantation

5. Secondary: Number of Participants With Treated Acute Rejection, Biopsy Proven Acute Rejection (BPAR), and Sub-clinical Rejection [Time Frame: 1 year post-transplant]

Measure Type	Secondary
Measure Title	Number of Participants With Treated Acute Rejection, Biopsy Proven Acute Rejection (BPAR), and Sub-clinical Rejection
Measure Description	Treated acute rejection is defined as an acute rejection, clinically suspected, whether biopsy-proven or not, which has been treated and confirmed by the investigator according to the response to therapy. BPAR was defined as a treated acute rejection confirmed by biopsy. The local pathologist graded biopsies according to the Banff (1997) criteria. A sub-clinical rejection was defined as a rejection identified by center driven biopsy, i.e. a biopsy performed routinely at some pre-defined time points after transplantation as per center practice in the absence of any clinical signs of rejection.
Time Frame	1 year post-transplant
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.
Intent-to-treat (ITT) population: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the

	target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	Tacrolimus
Number of Participants Analyzed [units: participants]	**182**	**169**
Number of Participants With Treated Acute Rejection, Biopsy Proven Acute Rejection (BPAR), and Sub-clinical Rejection [units: Participants]		
Treated acute rejection	**28**	**22**
Biopsy prove acute rejection (BPAR)	**28**	**19**
Sub-clinical rejection	**4**	**4**

No statistical analysis provided for Number of Participants With Treated Acute Rejection, Biopsy Proven Acute Rejection (BPAR), and Sub-clinical Rejection

6. Secondary: Number of Participants With Combined Endpoint of Death or Graft Loss or Biopsy Proven Acute Rejection (BPAR) [Time Frame: 1 year post-transplant]

Measure Type	Secondary
Measure Title	Number of Participants With Combined Endpoint of Death or Graft Loss or Biopsy Proven Acute Rejection (BPAR)
Measure Description	BPAR was defined as a treated acute rejection confirmed by biopsy. The local pathologist graded biopsies according to the Banff (1997) criteria. Graft loss was considered to have occurred when allograft was presumed to be lost if a patient had a liver re-transplant or died.
Time Frame	1 year post-transplant
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.
Intent-to-treat (ITT) population: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	Tacrolimus
Number of Participants Analyzed [units: participants]	**182**	**169**
Number of Participants With Combined Endpoint of Death or Graft Loss or Biopsy Proven Acute Rejection (BPAR) [units: Participants]	**45**	**42**

No statistical analysis provided for Number of Participants With Combined Endpoint of Death or Graft Loss or Biopsy Proven Acute Rejection (BPAR)

7. Secondary: Number of Participants With Death or Re-transplantation Due to Recurrence of Hepatitis C Cirrhosis [Time Frame: 1 year post-transplant]

Measure Type	Secondary
Measure Title	Number of Participants With Death or Re-transplantation Due to Recurrence of Hepatitis C Cirrhosis
Measure Description	Cirrhosis was resulted due to the recurrence of the hepatitis C virus infection in the transplanted liver.
Time Frame	1 year post-transplant
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.
Intent-to-treat (ITT) population: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	Tacrolimus
Number of Participants Analyzed [units: participants]	**182**	**169**
Number of Participants With Death or Re-transplantation Due to Recurrence of Hepatitis C Cirrhosis [units: Participants]	**16**	**17**

No statistical analysis provided for Number of Participants With Death or Re-transplantation Due to Recurrence of Hepatitis C Cirrhosis

8. Secondary: Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant (Intent to Treat Population) [Time Frame: 1 year post-transplant]

Measure Type	Secondary
Measure Title	Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant (Intent to Treat Population)
Measure Description	Assessment of hepatic fibrosis was performed with liver biopsies at Day 1, Month 6, 12 and 24, read centrally by two independent pathologists blinded to treatment arm and time of biopsy. Ishak-Knodell score was used to stage liver disease; 0= None; 1= Portal fibrosis (some); 2= Portal fibrosis (most); 3= Bridging fibrosis (few); 4= Bridging fibrosis (many); 5 = Incomplete cirrhosis; 6 = Cirrhosis. Higher score indicates greater fibrosis.
Time Frame	1 year post-transplant
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-To-Treat (ITT) population consisted of all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**182**	**169**
Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant (Intent to Treat Population) [units: Participants]	**63**	**54**

No statistical analysis provided for Number of Participants With Fibrosis Score 2 or Above [Ishak-Knodell Fibrosis Score (FS) ≥ 2] Within 1 Year Post-transplant (Intent to Treat Population)

9. Secondary: Mean Value of Liver Function Tests at 1 Year Post-transplantation [Time Frame: 1 year post-transplant]

Measure Type	Secondary
Measure Title	Mean Value of Liver Function Tests at 1 Year Post-transplantation
Measure Description	The mean value (in Units per liter, IU/L) of following tests were calculated at 1 year post-transplant: • Serum glutamic pyruvic transaminase (SGPT) • Serum Glutamic Oxaloacetic Transaminase (SGOT) • Bilirubin • Alkaline Phosphate

	• γ-Glutamyltransferase (GGT)
Time Frame	1 year post-transplant
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: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment. "n" is number participants with assessable data in each category.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**112**	**115**
Mean Value of Liver Function Tests at 1 Year Post-transplantation [units: IU/L] Mean (Standard Deviation)		
SGPT (n= 112, 112)	**100.5 (178.8)**	**81.7 (82.5)**
SGOT (n= 112,112)	**92.0 (122.3)**	**72.8 (98.2)**
Bilirubin (n= 111, 115)	**40.3 (85.5)**	**19.3 (27.9)**
Alkaline Phosphate (n= 111, 115)	**174.7 (152.9)**	**152.9 (127.3)**
GGT (n= 103, 110)	**182.2 (224.3)**	**168.5 (278.7)**

No statistical analysis provided for Mean Value of Liver Function Tests at 1 Year Post-transplantation

10. Secondary: Log-transformed Hepatitis C Virus Ribonucleic Acid (HCV RNA) Values up to 1 Year Post Transplant [Time Frame: Pre-transplant (Day 1), Day , Day 8, Day 29, Month 6 and 12 post- transplant]

Measure Type	Secondary
Measure Title	Log-transformed Hepatitis C Virus Ribonucleic Acid (HCV RNA) Values up to 1 Year Post Transplant
Measure Description	HCV RNA was measured (IU/μL)centrally pre-transplant (Day 1) and at 48 hours (Day 3), Day 8 and 29, Month 6 and 12 post-transplant and concomitantly to any additional biopsies performed.
Time Frame	Pre-transplant (Day 1), Day , Day 8, Day 29, Month 6 and 12 post- transplant
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: all patients as randomized that were transplanted, received at least one dose of study drug and had at least one post-baseline efficacy assessment. "n" in each of the categories is the number of participants with data at the given time point.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	**Tacrolimus**
Number of Participants Analyzed [units: participants]	**182**	**169**
Log-transformed Hepatitis C Virus Ribonucleic Acid (HCV RNA) Values up to 1 Year Post Transplant [units: IU/µL] Mean (Standard Deviation)		
Day 1 (n=116, 111)	**0.71 (0.887)**	**0.62 (0.809)**
Day 3 (n= 136, 120)	**0.98 (1.112)**	**0.91 (1.024)**
Day 8 (n= 122, 117)	**1.58 (1.569)**	**1.45 (1.557)**
Day 29 (n=128, 109)	**2.56 (1.658)**	**2.74 (1.439)**
Month 6 (n=96, 98)	**3.45 (1.069)**	**3.14 (1.332)**
Month 12 (n= 85, 88)	**3.17 (1.246)**	**3.13 (1.385)**

No statistical analysis provided for Log-transformed Hepatitis C Virus Ribonucleic Acid (HCV RNA) Values up to 1 Year Post Transplant

11. Secondary: Percentage of Participants With an Increase of at Least 1 Stage in Fibrosis [Time Frame: Between 1 and 2 years]

Measure Type	Secondary
Measure Title	Percentage of Participants With an Increase of at Least 1 Stage in Fibrosis
Measure Description	Assessment of hepatic fibrosis was performed with liver biopsies at Day 1, Month 6, 12 and 24, read centrally by two independent pathologists blinded to treatment arm and time of biopsy. Ishak-Knodell score was used to stage liver disease; 0= None; 1= Portal fibrosis (some); 2= Portal fibrosis (most); 3= Bridging fibrosis (few); 4= Bridging fibrosis (many); 5 = Incomplete cirrhosis; 6 = Cirrhosis. Higher score indicates greater fibrosis. An increase of at least 1 stage demonstrated a worsening of the disease, i.e. the transition from one score to the next higher one.
Time Frame	Between 1 and 2 years
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 outcome measure was not analyzed because of premature termination of study.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	Tacrolimus
Number of Participants Analyzed [units: participants]	**0**	**0**
Percentage of Participants With an Increase of at Least 1 Stage in Fibrosis [units: Percentage of participants]		

No statistical analysis provided for Percentage of Participants With an Increase of at Least 1 Stage in Fibrosis

12. Secondary: Mean Fibrosis Score [Time Frame: At 1and 2 years and its evolution over time]

Measure Type	Secondary
Measure Title	Mean Fibrosis Score
Measure Description	Assessment of hepatic fibrosis was performed with liver biopsies at Day 1, Month 6, 12 and 24, read centrally by two independent pathologists blinded to treatment arm and time of biopsy. Ishak-Knodell score was used to stage liver disease; 0= None; 1= Portal fibrosis (some); 2= Portal fibrosis (most); 3= Bridging fibrosis (few); 4= Bridging fibrosis (many); 5 = Incomplete cirrhosis; 6 = Cirrhosis. Higher score indicates greater fibrosis. The mean score was equivalent to mean of IK at 1 and 2 years (evolution over time).
Time Frame	At 1and 2 years and its evolution over time
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This outcome was not analyzed because of premature termination of study.

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Measured Values

	Cyclosporin A	Tacrolimus

Number of Participants Analyzed [units: participants]	**0**	**0**
Mean Fibrosis Score [units: units on a scale] Mean (Standard Deviation)		

No statistical analysis provided for Mean Fibrosis Score

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Serious Adverse Events

	Cyclosporin A	Tacrolimus
Total, serious adverse events		
# participants affected / at risk	**148/184 (80.43%)**	**138/172 (80.23%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Leukopenia † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Lymphadenopathy † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Neutropenia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Pancytopenia † 1		
# participants affected / at risk	**0/184 (0.00%)**	**2/172 (1.16%)**
Thrombocytopenia † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Cardiac disorders		
Atrial tachycardia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Cardiac arrest † 1		

# participants affected / at risk	**1/184 (0.54%)**	**2/172 (1.16%)**
Cardiac disorder † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Cardiac failure † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Cardio-respiratory arrest † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Cardiopulmonary failure † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Myocardial infarction † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Pericardial effusion † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Ventricular tachycardia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Gastrointestinal disorders		
Abdominal adhesions † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Abdominal distension † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Abdominal pain † 1		
# participants affected / at risk	**3/184 (1.63%)**	**9/172 (5.23%)**
Abdominal pain upper † 1		
# participants affected / at risk	**1/184 (0.54%)**	**2/172 (1.16%)**
Abdominal rigidity † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Ascites † 1		
# participants affected / at risk	**2/184 (1.09%)**	**2/172 (1.16%)**
Colitis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Constipation † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Diarrhoea † 1		
# participants affected / at risk	**0/184 (0.00%)**	**2/172 (1.16%)**
Duodenitis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Dysphagia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Epigastric discomfort † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Faeces pale † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**

Ileus † 1		
# participants affected / at risk	**1/184 (0.54%)**	**2/172 (1.16%)**
Inguinal hernia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**2/172 (1.16%)**
Inguinal hernia, obstructive † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Intestinal strangulation † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Localised intraabdominal fluid collection † 1		
# participants affected / at risk	**0/184 (0.00%)**	**4/172 (2.33%)**
Mechanical ileus † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Melaena † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Nausea † 1		
# participants affected / at risk	**3/184 (1.63%)**	**1/172 (0.58%)**
Pancreatitis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Umbilical hernia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Upper gastrointestinal haemorrhage † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Vomiting † 1		
# participants affected / at risk	**6/184 (3.26%)**	**2/172 (1.16%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Chest pain † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Effusion † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
General physical health deterioration † 1		
# participants affected / at risk	**0/184 (0.00%)**	**2/172 (1.16%)**
Hernia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Hernia obstructive † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Hernia pain † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Impaired healing † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Multi-organ failure † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Non-cardiac chest pain † 1		

# participants affected / at risk	1/184 (0.54%)	1/172 (0.58%)
Oedema peripheral † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Pain † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Pyrexia † 1		
# participants affected / at risk	13/184 (7.07%)	9/172 (5.23%)
Hepatobiliary disorders		
Acute hepatic failure † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Bile duct necrosis † 1		
# participants affected / at risk	1/184 (0.54%)	1/172 (0.58%)
Bile duct obstruction † 1		
# participants affected / at risk	1/184 (0.54%)	3/172 (1.74%)
Bile duct stenosis † 1		
# participants affected / at risk	8/184 (4.35%)	3/172 (1.74%)
Bile duct stone † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Biliary cirrhosis † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Biliary ischaemia † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Biloma † 1		
# participants affected / at risk	1/184 (0.54%)	2/172 (1.16%)
Cholangitis † 1		
# participants affected / at risk	9/184 (4.89%)	2/172 (1.16%)
Cholestasis † 1		
# participants affected / at risk	1/184 (0.54%)	1/172 (0.58%)
Haemobilia † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Hepatic artery stenosis † 1		
# participants affected / at risk	2/184 (1.09%)	2/172 (1.16%)
Hepatic artery thrombosis † 1		
# participants affected / at risk	1/184 (0.54%)	3/172 (1.74%)
Hepatic failure † 1		
# participants affected / at risk	5/184 (2.72%)	1/172 (0.58%)
Hepatic function abnormal † 1		
# participants affected / at risk	2/184 (1.09%)	3/172 (1.74%)
Hepatic haemorrhage † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Hepatic infiltration eosinophilic † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Hepatic vein thrombosis † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)

Hepatitis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Hepatitis cholestatic † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Hyperbilirubinaemia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Hypertransaminasaemia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Ischaemic hepatitis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Portal vein thrombosis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Immune system disorders		
Drug hypersensitivity † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Liver transplant rejection † 1		
# participants affected / at risk	**11/184 (5.98%)**	**7/172 (4.07%)**
Transplant rejection † 1		
# participants affected / at risk	**2/184 (1.09%)**	**2/172 (1.16%)**
Infections and infestations		
Abdominal abscess † 1		
# participants affected / at risk	**1/184 (0.54%)**	**2/172 (1.16%)**
Abdominal sepsis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Abdominal wall abscess † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Bacteraemia † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Bone abscess † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Bronchitis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Bronchopneumonia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Cellulitis † 1		
# participants affected / at risk	**2/184 (1.09%)**	**1/172 (0.58%)**
Clostridium difficile colitis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Cytomegalovirus hepatitis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**2/172 (1.16%)**
Cytomegalovirus infection † 1		
# participants affected / at risk	**7/184 (3.80%)**	**1/172 (0.58%)**
Cytomegalovirus viraemia † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**

Enterobacter infection † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Enterocolitis infectious † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Escherichia sepsis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Fungal infection † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Gastroenteritis † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Gastroenteritis viral † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Groin abscess † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Hepatic infection † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Hepatitis C † 1		
# participants affected / at risk	**77/184 (41.85%)**	**65/172 (37.79%)**
Herpes zoster † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Infective exacerbation of chronic obstructive airways disease † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Intervertebral discitis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Liver abscess † 1		
# participants affected / at risk	**3/184 (1.63%)**	**0/172 (0.00%)**
Lung infection † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Neurological infection † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Osteomyelitis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Pericarditis fungal † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Peritonitis bacterial † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Pneumonia † 1		
# participants affected / at risk	**2/184 (1.09%)**	**7/172 (4.07%)**
Pneumonia bacterial † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Respiratory tract infection † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Sepsis † 1		
# participants affected / at risk	**8/184 (4.35%)**	**5/172 (2.91%)**

Septic shock † 1		
# participants affected / at risk	**0/184 (0.00%)**	**2/172 (1.16%)**
Sinusitis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Staphylococcal sepsis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Tuberculosis liver † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Urinary tract infection † 1		
# participants affected / at risk	**1/184 (0.54%)**	**3/172 (1.74%)**
Wound infection † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Injury, poisoning and procedural complications		
Ankle fracture † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Biliary anastomosis complication † 1		
# participants affected / at risk	**1/184 (0.54%)**	**4/172 (2.33%)**
Chemical peritonitis † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Collapse of lung † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Complications of transplanted liver † 1		
# participants affected / at risk	**3/184 (1.63%)**	**10/172 (5.81%)**
Gastrointestinal injury † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Graft loss † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Hepatic haematoma † 1		
# participants affected / at risk	**3/184 (1.63%)**	**0/172 (0.00%)**
Incision site haemorrhage † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Incisional hernia † 1		
# participants affected / at risk	**3/184 (1.63%)**	**1/172 (0.58%)**
Limb traumatic amputation † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Post procedural bile leak † 1		
# participants affected / at risk	**5/184 (2.72%)**	**4/172 (2.33%)**
Post procedural haemorrhage † 1		
# participants affected / at risk	**2/184 (1.09%)**	**1/172 (0.58%)**
Postoperative fever † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Procedural site reaction † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Seroma † 1		

# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Skin laceration † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Spinal compression fracture † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Subdural haematoma † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Therapeutic agent toxicity † 1		
# participants affected / at risk	1/184 (0.54%)	2/172 (1.16%)
Vascular pseudoaneurysm † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Wound decomposition † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Investigations		
Blood bilirubin increased † 1		
# participants affected / at risk	1/184 (0.54%)	2/172 (1.16%)
Blood creatine phosphokinase increased † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Blood creatinine increased † 1		
# participants affected / at risk	3/184 (1.63%)	0/172 (0.00%)
Blood pressure increased † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Hepatic enzyme increased † 1		
# participants affected / at risk	1/184 (0.54%)	2/172 (1.16%)
Hepatitis C virus test positive † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Liver function test abnormal † 1		
# participants affected / at risk	14/184 (7.61%)	9/172 (5.23%)
Transaminases increased † 1		
# participants affected / at risk	2/184 (1.09%)	0/172 (0.00%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	1/184 (0.54%)	1/172 (0.58%)
Diabetes mellitus † 1		
# participants affected / at risk	0/184 (0.00%)	4/172 (2.33%)
Diabetic ketoacidosis † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Fluid overload † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Hyperglycaemia † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Hyperkalaemia † 1		
# participants affected / at risk	1/184 (0.54%)	1/172 (0.58%)
Hypovolaemia † 1		

# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Malnutrition † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Type 2 diabetes mellitus † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	1/184 (0.54%)	3/172 (1.74%)
Myositis † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
B-cell lymphoma † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Hepatic cancer metastatic † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Hepatic neoplasm malignant † 1		
# participants affected / at risk	1/184 (0.54%)	1/172 (0.58%)
Lung neoplasm † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Lung neoplasm malignant † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Lymphoma † 1		
# participants affected / at risk	0/184 (0.00%)	2/172 (1.16%)
Metastases to lung † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Non-Hodgkin's lymphoma † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Prostate cancer † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Seminoma † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Tongue neoplasm malignant stage unspecified † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Transitional cell carcinoma † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Nervous system disorders		
Cerebral haemorrhage † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Cerebral ischaemia † 1		
# participants affected / at risk	1/184 (0.54%)	0/172 (0.00%)
Cerebrovascular accident † 1		
# participants affected / at risk	0/184 (0.00%)	1/172 (0.58%)
Convulsion † 1		
# participants affected / at risk	2/184 (1.09%)	1/172 (0.58%)

Dizziness † 1		
# participants affected / at risk	**0/184 (0.00%)**	**2/172 (1.16%)**
Encephalopathy † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Haemorrhage intracranial † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Haemorrhagic stroke † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Headache † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Hypertensive encephalopathy † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Migraine † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Neurological symptom † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Neurotoxicity † 1		
# participants affected / at risk	**1/184 (0.54%)**	**2/172 (1.16%)**
Reversible posterior leukoencephalopathy syndrome † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Somnolence † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Subarachnoid haemorrhage † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Transient ischaemic attack † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Tremor † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Psychiatric disorders		
Alcoholism † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Delirium † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Mental status changes † 1		
# participants affected / at risk	**3/184 (1.63%)**	**1/172 (0.58%)**
Psychotic disorder † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Substance abuse † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Transient psychosis † 1		
# participants affected / at risk	**3/184 (1.63%)**	**0/172 (0.00%)**
Renal and urinary disorders		
Acute prerenal failure † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**

Anuria † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Nephrotic syndrome † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Renal failure † 1		
# participants affected / at risk	**6/184 (3.26%)**	**3/172 (1.74%)**
Renal failure acute † 1		
# participants affected / at risk	**14/184 (7.61%)**	**6/172 (3.49%)**
Renal impairment † 1		
# participants affected / at risk	**2/184 (1.09%)**	**2/172 (1.16%)**
Renal tubular necrosis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Acute respiratory failure † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Brain hypoxia † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Dyspnoea † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Haemothorax † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Hyperventilation † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Pleural effusion † 1		
# participants affected / at risk	**5/184 (2.72%)**	**2/172 (1.16%)**
Pleurisy † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Pneumonitis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Pulmonary embolism † 1		
# participants affected / at risk	**1/184 (0.54%)**	**2/172 (1.16%)**
Pulmonary oedema † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Respiratory distress † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Respiratory failure † 1		
# participants affected / at risk	**5/184 (2.72%)**	**5/172 (2.91%)**
Skin and subcutaneous tissue disorders		
Night sweats † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**

Stasis dermatitis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**2/172 (1.16%)**
Haemodynamic instability † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Hypertension † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Hypertensive crisis † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Hypotension † 1		
# participants affected / at risk	**2/184 (1.09%)**	**0/172 (0.00%)**
Intra-abdominal haematoma † 1		
# participants affected / at risk	**1/184 (0.54%)**	**0/172 (0.00%)**
Intra-abdominal haemorrhage † 1		
# participants affected / at risk	**2/184 (1.09%)**	**2/172 (1.16%)**
Malignant hypertension † 1		
# participants affected / at risk	**1/184 (0.54%)**	**1/172 (0.58%)**
Thrombosis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Venoocclusive disease † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**
Venous thrombosis † 1		
# participants affected / at risk	**0/184 (0.00%)**	**1/172 (0.58%)**

† 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
Cyclosporin A	The first administration of Cyclosporin A (CsA) was within the first 24 hours post-transplantation at an initial dose of 10-15mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally, via a nasogastric (NG) tube or intravenously (i.v). Twice daily (b.i.d.) administration was maintained throughout the study period. During the study, it was recommended that the dose of CsA was adjusted, as necessary, to achieve and maintain the C2 or C0 blood CsA concentration within the target ranges.
Tacrolimus	Tacrolimus was administered within the first 24 hours post-transplantation at an initial dose of 0.1-0.15 mg/kg/day in 2 divided doses (twice daily at 12-hour interval) either orally or via a nasogastric (NG) tube or intravenously (i.v). Twice daily

	(b.i.d.) administration was maintained throughout the study period. During the course of the study, the dose of tacrolimus was adjusted as necessary to achieve and maintain the C0 tacrolimus concentrations within target ranges.

Other Adverse Events

	Cyclosporin A	Tacrolimus
Total, other (not including serious) adverse events		
# participants affected / at risk	**182/184 (98.91%)**	**167/172 (97.09%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**51/184 (27.72%)**	**54/172 (31.40%)**
Coagulopathy † 1		
# participants affected / at risk	**3/184 (1.63%)**	**9/172 (5.23%)**
Leukopenia † 1		
# participants affected / at risk	**17/184 (9.24%)**	**10/172 (5.81%)**
Thrombocytopenia † 1		
# participants affected / at risk	**23/184 (12.50%)**	**28/172 (16.28%)**
Gastrointestinal disorders		
Abdominal distension † 1		
# participants affected / at risk	**14/184 (7.61%)**	**7/172 (4.07%)**
Abdominal pain † 1		
# participants affected / at risk	**31/184 (16.85%)**	**44/172 (25.58%)**
Abdominal pain upper † 1		
# participants affected / at risk	**9/184 (4.89%)**	**14/172 (8.14%)**
Ascites † 1		
# participants affected / at risk	**31/184 (16.85%)**	**29/172 (16.86%)**
Constipation † 1		
# participants affected / at risk	**64/184 (34.78%)**	**62/172 (36.05%)**
Diarrhoea † 1		
# participants affected / at risk	**41/184 (22.28%)**	**57/172 (33.14%)**
Dyspepsia † 1		
# participants affected / at risk	**15/184 (8.15%)**	**14/172 (8.14%)**
Nausea † 1		
# participants affected / at risk	**55/184 (29.89%)**	**59/172 (34.30%)**
Vomiting † 1		
# participants affected / at risk	**30/184 (16.30%)**	**25/172 (14.53%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**15/184 (8.15%)**	**9/172 (5.23%)**
Fatigue † 1		
# participants affected / at risk	**24/184 (13.04%)**	**19/172 (11.05%)**
Generalised oedema † 1		
# participants affected / at risk	**12/184 (6.52%)**	**12/172 (6.98%)**
Non-cardiac chest pain † 1		
# participants affected / at risk	**7/184 (3.80%)**	**13/172 (7.56%)**

Oedema peripheral † 1		
# participants affected / at risk	**61/184 (33.15%)**	**58/172 (33.72%)**
Pyrexia † 1		
# participants affected / at risk	**52/184 (28.26%)**	**47/172 (27.33%)**
Hepatobiliary disorders		
Bile duct stenosis † 1		
# participants affected / at risk	**11/184 (5.98%)**	**12/172 (6.98%)**
Cholestasis † 1		
# participants affected / at risk	**10/184 (5.43%)**	**10/172 (5.81%)**
Hyperbilirubinaemia † 1		
# participants affected / at risk	**13/184 (7.07%)**	**7/172 (4.07%)**
Infections and infestations		
Cytomegalovirus infection † 1		
# participants affected / at risk	**16/184 (8.70%)**	**5/172 (2.91%)**
Hepatitis C † 1		
# participants affected / at risk	**19/184 (10.33%)**	**21/172 (12.21%)**
Nasopharyngitis † 1		
# participants affected / at risk	**10/184 (5.43%)**	**13/172 (7.56%)**
Pneumonia † 1		
# participants affected / at risk	**6/184 (3.26%)**	**15/172 (8.72%)**
Urinary tract infection † 1		
# participants affected / at risk	**24/184 (13.04%)**	**16/172 (9.30%)**
Injury, poisoning and procedural complications		
Incision site pain † 1		
# participants affected / at risk	**33/184 (17.93%)**	**27/172 (15.70%)**
Post procedural bile leak † 1		
# participants affected / at risk	**8/184 (4.35%)**	**9/172 (5.23%)**
Post procedural discharge † 1		
# participants affected / at risk	**6/184 (3.26%)**	**10/172 (5.81%)**
Procedural pain † 1		
# participants affected / at risk	**50/184 (27.17%)**	**59/172 (34.30%)**
Investigations		
Blood bilirubin increased † 1		
# participants affected / at risk	**15/184 (8.15%)**	**6/172 (3.49%)**
Blood creatinine increased † 1		
# participants affected / at risk	**35/184 (19.02%)**	**23/172 (13.37%)**
Blood glucose increased † 1		
# participants affected / at risk	**4/184 (2.17%)**	**9/172 (5.23%)**
Blood potassium decreased † 1		
# participants affected / at risk	**10/184 (5.43%)**	**9/172 (5.23%)**
Haemoglobin decreased † 1		
# participants affected / at risk	**8/184 (4.35%)**	**11/172 (6.40%)**
Liver function test abnormal † 1		
# participants affected / at risk	**31/184 (16.85%)**	**25/172 (14.53%)**

Urine output decreased † 1		
# participants affected / at risk	**17/184 (9.24%)**	**16/172 (9.30%)**
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	**21/184 (11.41%)**	**16/172 (9.30%)**
Diabetes mellitus † 1		
# participants affected / at risk	**26/184 (14.13%)**	**28/172 (16.28%)**
Fluid overload † 1		
# participants affected / at risk	**11/184 (5.98%)**	**13/172 (7.56%)**
Hyperglycaemia † 1		
# participants affected / at risk	**46/184 (25.00%)**	**49/172 (28.49%)**
Hyperkalaemia † 1		
# participants affected / at risk	**27/184 (14.67%)**	**28/172 (16.28%)**
Hypoalbuminaemia † 1		
# participants affected / at risk	**13/184 (7.07%)**	**14/172 (8.14%)**
Hypocalcaemia † 1		
# participants affected / at risk	**17/184 (9.24%)**	**17/172 (9.88%)**
Hypokalaemia † 1		
# participants affected / at risk	**33/184 (17.93%)**	**29/172 (16.86%)**
Hypomagnesaemia † 1		
# participants affected / at risk	**39/184 (21.20%)**	**43/172 (25.00%)**
Hyponatraemia † 1		
# participants affected / at risk	**11/184 (5.98%)**	**6/172 (3.49%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**10/184 (5.43%)**	**11/172 (6.40%)**
Back pain † 1		
# participants affected / at risk	**38/184 (20.65%)**	**25/172 (14.53%)**
Muscle spasms † 1		
# participants affected / at risk	**11/184 (5.98%)**	**16/172 (9.30%)**
Musculoskeletal pain † 1		
# participants affected / at risk	**13/184 (7.07%)**	**5/172 (2.91%)**
Pain in extremity † 1		
# participants affected / at risk	**11/184 (5.98%)**	**14/172 (8.14%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**8/184 (4.35%)**	**11/172 (6.40%)**
Headache † 1		
# participants affected / at risk	**45/184 (24.46%)**	**39/172 (22.67%)**
Tremor † 1		
# participants affected / at risk	**26/184 (14.13%)**	**30/172 (17.44%)**
Psychiatric disorders		
Agitation † 1		
# participants affected / at risk	**16/184 (8.70%)**	**24/172 (13.95%)**

Anxiety † 1		
# participants affected / at risk	**30/184 (16.30%)**	**21/172 (12.21%)**
Confusional state † 1		
# participants affected / at risk	**9/184 (4.89%)**	**15/172 (8.72%)**
Depression † 1		
# participants affected / at risk	**17/184 (9.24%)**	**16/172 (9.30%)**
Insomnia † 1		
# participants affected / at risk	**65/184 (35.33%)**	**64/172 (37.21%)**
Renal and urinary disorders		
Oliguria † 1		
# participants affected / at risk	**22/184 (11.96%)**	**20/172 (11.63%)**
Renal failure † 1		
# participants affected / at risk	**19/184 (10.33%)**	**18/172 (10.47%)**
Renal failure acute † 1		
# participants affected / at risk	**23/184 (12.50%)**	**16/172 (9.30%)**
Renal impairment † 1		
# participants affected / at risk	**21/184 (11.41%)**	**15/172 (8.72%)**
Respiratory, thoracic and mediastinal disorders		
Atelectasis † 1		
# participants affected / at risk	**11/184 (5.98%)**	**11/172 (6.40%)**
Cough † 1		
# participants affected / at risk	**14/184 (7.61%)**	**14/172 (8.14%)**
Dyspnoea † 1		
# participants affected / at risk	**22/184 (11.96%)**	**24/172 (13.95%)**
Pleural effusion † 1		
# participants affected / at risk	**25/184 (13.59%)**	**31/172 (18.02%)**
Pulmonary oedema † 1		
# participants affected / at risk	**7/184 (3.80%)**	**9/172 (5.23%)**
Skin and subcutaneous tissue disorders		
Pruritus † 1		
# participants affected / at risk	**21/184 (11.41%)**	**19/172 (11.05%)**
Rash † 1		
# participants affected / at risk	**11/184 (5.98%)**	**5/172 (2.91%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**92/184 (50.00%)**	**69/172 (40.12%)**
Hypotension † 1		
# participants affected / at risk	**20/184 (10.87%)**	**15/172 (8.72%)**

† 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
This study was prematurely discontinued due to poor recruitment. Since only a small patient group could be analyzed for primary outcome measure, robust conclusions on the effect of the two calcineurin inhibitors on the fibrosis score cannot be drawn.

More Information

Hide More Information

Certain Agreements:

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

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00260208 History of Changes
Other Study ID Numbers:	**COLO400A2426**
Study First Received:	November 30, 2005
Results First Received:	September 14, 2011
Last Updated:	December 2, 2011
Health Authority:	United States: Institutional Review Board