ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: August 10, 2018

ClinicalTrials.gov ID: NCT00991510

Study Identification

Unique Protocol ID:	116B8
Brief Title:	Comparative Bioavailability of Myfenax® and CellCept® in Kidney Transplant Patients
Official Title:	Comparative Bioavailability of Myfenax® (Teva) and CellCept® (Roche) in Stable Patients After Renal Transplantation
Secondary IDs:	2009-010562-31 [EudraCT Number]

Study Status

Record Verification:	August 2018
Overall Status:	Terminated [Slow recruitment and lack of time to product launch]
Study Start:	August 2009 []
Primary Completion:	October 2010 [Actual]
Study Completion:	March 2011 [Actual]

Sponsor/Collaborators

Sponsor:	Teva Pharmaceutical Industries
Responsible Party:	Sponsor
Collaborators:	Parexel

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: EK Nr. 139/2009 [redacted] Address: [redacted]
Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary:	The purpose of the study is to further investigate how much of the drug substance “mycophenolate mofetil” can be found in the blood of patients with kidney or renal transplants when treated with Myfenax® or CellCept®. Additionally, the safety and side effects of the two products will be compared. All information already available on these products indicates that the safety profiles of the two products will be the same.
Detailed Description:	

Conditions

Conditions:	Stable Renal Transplant Recipients
Keywords:	renal transplantation mycophenolate mofetil pharmacokinetics immunosuppression

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Interventional Study Model:	Crossover Assignment
Number of Arms:	2

Masking:	None (Open Label)
Allocation:	Randomized
Enrollment:	43 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Reference/Test/Test The reference product was CellCept® and test product was Myfenax®. In period I, participants received CellCept on Days 1-14. In period II, participants crossed-over to receive Myfenax on Days 15-28. In period III, participants received Myfenax until the end of the study (Days 29-112). Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.	Drug: mycophenolate mofetil (Myfenax) Each participant received at least 500 mg orally, twice daily (morning and evening) during those study periods labeled as 'T' (test drug). Participants receive the dose equivalent to the pre-study dose (within the recommended therapeutic range) of mycophenolate mofetil. Other Names: • Myfenax® Drug: mycophenolate mofetil (Cellcept) Each participant received at least 500 mg orally, twice daily (morning and evening) during those study periods labeled as 'R' (reference drug). Participants receive the dose equivalent to the pre-study dose (within the recommended therapeutic range) of mycophenolate mofetil. Other Names: • CellCept®
Experimental: Test/Reference/Reference The test product was Myfenax® and the reference product was CellCept®. In period I, participants received Myfenax on Days 1-14. In period II, participants crossed-over to receive CellCept on Days 15-28. In period III, participants received CellCept until the end of the study (Days 29-112). Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.	Drug: mycophenolate mofetil (Myfenax) Each participant received at least 500 mg orally, twice daily (morning and evening) during those study periods labeled as 'T' (test drug). Participants receive the dose equivalent to the pre-study dose (within the recommended therapeutic range) of mycophenolate mofetil. Other Names: • Myfenax® Drug: mycophenolate mofetil (Cellcept) Each participant received at least 500 mg orally, twice daily (morning and evening) during those study periods labeled as 'R' (reference drug). Participants receive the dose equivalent to the pre-study dose (within the recommended therapeutic range) of mycophenolate mofetil. Other Names: • CellCept®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Renal transplant recipients at least 12 months post-transplantation aged ≥ 18 years.
- Maintenance treatment with mycophenolate mofetil (in combination with tacrolimus with or without corticosteroids).
- Stable dose of mycophenolate mofetil (≥ 500 mg twice daily) with no changes in immunosuppressive regimen for at least 6 weeks prior to the start of the study.
- Stable renal graft function for at least 3 months.
- Female patients must be either post-menopausal for ≥ 1 year, be surgically sterilized or a negative pregnancy test will be required immediately prior to study entry and such patients must continue to use effective contraception.
- Willingness to undergo the study-related procedures.
- Ability to comprehend and willingness to sign informed consent form.

Exclusion Criteria:

- History of allergy to mycophenolate mofetil, mycophenolic acid or any of the ingredients.
- Multi-organ recipients (e.g., kidney and pancreas) or previous transplant with any organ other than kidney.
- Rejection within the past 6 months prior to the start of the study.
- Severe clinically relevant co-existing disease.
- History of cancer other than skin cancer that has been cured.
- History of serious clinically relevant digestive system disease during the last 12 months prior to start of the study.
- Known or suspected hereditary deficiency of hypoxanthine-guanine-phosphoribosyltransferase (e.g., Lesch-Nyhan syndrome, Kelley-Seegmiller syndrome).
- Known or suspected liver impairment.
- Clinically significant thrombocytopenia, anaemia, leukopenia, or neutropenia
- Clinically significant laboratory and/or physical changes during the last 2 months prior to the start of the study.
- Use of azathioprine, cholestyramine, sevelamer, or probenecid within 2 weeks prior to the first administration of study medication.
- Change in concomitant medication during the 6 weeks prior to start of the study.
- Use of any drug, prescribed or over-the-counter, (except stable concomitant medication) within 2 weeks prior to the first administration of study medication.
- Planned or expected requirement for the use of live attenuated vaccines during the study.

- Positive testing for HIV, Hepatitis B and C.
- Clinical symptoms or laboratory evidence of cytomegalovirus infection in the last 6 month.
- Pregnant or breast-feeding women.
- Women of childbearing potential unable or unwilling to practice effective contraceptive measures for the duration of the study and for 6 weeks after the end of the study.
- History of known or suspected alcohol or drug abuse.
- Any other condition of the patient that, in the opinion of the investigator may compromise evaluation of the study treatment or may jeopardize patient's compliance or adherence to protocol requirements.
- Previous enrollment in this study or participation in any other drug investigational trial within the past 6 weeks prior to enrollment.

Contacts/Locations

Central Contact Person: [redacted]

Central Contact Backup:

Study Officials: [redacted]

Locations:

IPDSharing

Plan to Share IPD:

References

Citations: [Study Results] Sunder-Plassmann G et al.: Results of a Comparative Bioavailability Study of Myfenax (Teva) and CellCept (Roche) in Stable Kidney Transplant Recipients. American Transplant Congress 2011. Abstract Number: 250308

[Study Results] Sunder-Plassmann G, Reinke P, Rath T, Wiecek A, Nowicki M, Moore R, Lutz J, Gaggl M, Ferkl M. Comparative pharmacokinetic study of two mycophenolate mofetil formulations in stable kidney transplant recipients. Transpl Int. 2012 Jun;25(6):680-6. doi: 10.1111/j.1432-2277.2012.01475.x. Epub 2012 Apr 16. PubMed 22500920

Links:

Available IPD/Information:

Participant Flow

Pre-assignment Details	A total of 100 subjects were planned. A total of 47 subjects were screened in the study. Four subjects were not randomised, i.e., two subjects withdrew consent, one subject had a protocol violation, and one subject was a screening failure (did not meet eligibility criteria).

Reporting Groups

	Description
Reference/Test/Test	The reference product was CellCept® and test product was Myfenax®. In period I, participants received CellCept on Days 1-14. In period II, participants crossed-over to receive Myfenax on Days 15-28. In period III, participants received Myfenax until the end of the study (Days 29-112). Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Test/Reference/Reference	The test product was Myfenax® and the reference product was CellCept®. In period I, participants received Myfenax on Days 1-14. In period II, participants crossed-over to receive CellCept on Days 15-28. In period III, participants received CellCept until the end of the study (Days 29-112). Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Period I (Days 1-14)

	Reference/Test/Test	Test/Reference/Reference
Started	22	21
Completed	21	21
Not Completed	1	0
Adverse Event	1	0

Period II (Days 15-28)

	Reference/Test/Test	Test/Reference/Reference
Started	21	21
Completed	21	21
Not Completed	0	0

Period III (Days 29-112)

	Reference/Test/Test	Test/Reference/Reference
Started	21	21
Completed	20	20
Not Completed	1	1
Adverse Event	1	1

Baseline Characteristics

Reporting Groups

	Description
Reference/Test/Test	The reference product was CellCept® and test product was Myfenax®. In period I, participants received CellCept on Days 1-14. In period II, participants crossed-over to receive Myfenax on Days 15-28. In period III, participants received Myfenax until the end of the study (Days 29-112). Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Test/Reference/Reference	The test product was Myfenax® and the reference product was CellCept®. In period I, participants received Myfenax on Days 1-14. In period II, participants crossed-over to receive CellCept on Days 15-28. In period III, participants received CellCept until the end of the study (Days 29-112). Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Baseline Measures

		Reference/Test/Test	Test/Reference/Reference	Total
Overall Number of Participants		22	21	43
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	22 participants	21 participants	43 participants
		49.7 (13.73)	51.7 (13.55)	50.7 (13.52)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	22 participants	21 participants	43 participants
	Female	11 50%	8 38.1%	19 44.19%
	Male	11 50%	13 61.9%	24 55.81%

		Reference/Test/Test	Test/Reference/Reference	Total
Race/Ethnicity, Customized Measure Type: Number Unit of measure: participants	Number Analyzed	22 participants	21 participants	43 participants
Asian		1	0	1
Caucasian		21	21	42
Height Mean (Standard Deviation) Unit of measure: meters	Number Analyzed	22 participants	21 participants	43 participants
		1.711 (0.1061)	1.718 (0.0983)	1.714 (0.1012)
Weight Mean (Standard Deviation) Unit of measure: kilograms	Number Analyzed	22 participants	21 participants	43 participants
		77.19 (14.856)	77.23 (15.661)	77.21 (15.072)
Body Mass Index Mean (Standard Deviation) Unit of measure: kg/m^2	Number Analyzed	22 participants	21 participants	43 participants
		26.24 (3.756)	25.93 (3.422)	26.09 (3.557)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Area Under the Plasma Concentration-time Curve (AUC(0-6h)) of Mycophenolate Mofetil
Measure Description	Area under the plasma concentration-time curve during a dosage interval at steady state (calculated using the trapezoidal rule, from t = 0 to t = 6 hours).
Time Frame	Day 14 and Day 28 (end of first two cross-over periods) before drug administration and at 30 min, 1 hour, 1.5, 2, 3, 4, 5, 6, 8, 10, and 12 hours after drug administration

Analysis Population Description

PK population. Two participants were excluded from the PK population: one dropped out of the study during the first period so had no PK samples. The other was omitted due to protocol violations.

Reporting Groups

	Description
CellCept	Timeframes in periods I and II when participants took CellCept in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Timeframes in periods I and II when participants took Myfenax in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Measured Values

	CellCept	Myfenax
Overall Number of Participants Analyzed	41	41
Area Under the Plasma Concentration-time Curve (AUC(0-6h)) of Mycophenolate Mofetil Mean (Standard Deviation) Unit of measure: hour* µg /ml	33.523 (15.1265)	31.100 (15.4198)

Statistical Analysis 1 for Area Under the Plasma Concentration-time Curve (AUC(0-6h)) of Mycophenolate Mofetil

Statistical Analysis Overview	Comparison Group Selection	CellCept, Myfenax
	Comments	A total of 100 subjects were planned to be enrolled, allowing for 10% drop-out rate. Based on previous single dose studies, the intra-subject coefficients of variation were 14% and 50% for AUC and Cmax, respectively. Based on the literature similar intra subject coefficients of variation were observed in steady-state patients. With these expected CV(%) and an expected ratio of Cmax within 0.95 and 1.05, the study should have a power of at least 80 % to show bioequivalence with 80 subjects.
	Type of Statistical Test	Non-Inferiority or Equivalence (legacy)
	Comments	Bioequivalence was accepted if the calculated 90 % CIs were within 0.80-1.25.

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [adjusted least-squares mean ratio]
	Estimated Value	0.923
	Confidence Interval	(2-Sided) 90%

		0.865 to 0.984
	Estimation Comments	[Not specified]

2. Primary Outcome Measure:

Measure Title	Area Under the Plasma Concentration-time Curve (AUC(0-tau)) of Mycophenolate Mofetil
Measure Description	For participants with a 0-12h profile: Area under the plasma concentration-time curve during a dosage interval at steady state (calculated using the trapezoidal rule, from t = 0 to t = 12 hours). For participants with a 0-6h profile: AUC(0-tau) was calculated based on AUC(0-6h) using the extrapolation formula according to Fleming.
Time Frame	Day 14 and Day 28 (end of first two cross-over periods) before drug administration and at 30 min, 1 hour, 1.5, 2, 3, 4, 5, 6, 8, 10, and 12 hours after drug administration

Analysis Population Description

PK population. Two participants were excluded from the PK population: one dropped out of the study during the first period so had no PK samples. The other was omitted due to protocol violations.

Reporting Groups

	Description
CellCept	Timeframes in periods I and II when participants took CellCept in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Timeframes in periods I and II when participants took Myfenax in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Measured Values

	CellCept	Myfenax
Overall Number of Participants Analyzed	41	41
Area Under the Plasma Concentration-time Curve (AUC(0-tau)) of Mycophenolate Mofetil Mean (Standard Deviation) Unit of measure: hour* µg /ml	49.846 (20.8278)	48.255 (21.2246)

Statistical Analysis 1 for Area Under the Plasma Concentration-time Curve (AUC(0-tau)) of Mycophenolate Mofetil

Statistical Analysis Overview	Comparison Group Selection	CellCept, Myfenax
	Comments	[Not specified]
	Type of Statistical Test	Non-Inferiority or Equivalence (legacy)

	Comments	Bioequivalence was accepted if the calculated 90 % CIs were within 0.80-1.25.

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [adjusted least-squares mean ratio]
	Estimated Value	0.959
	Confidence Interval	(2-Sided) 90% 0.899 to 1.023
	Estimation Comments	[Not specified]

3. Primary Outcome Measure:

Measure Title	Maximum Observed Plasma Concentration (Cmax) of Mycophenolate Mofetil
Measure Description	Cmax was directly obtained from measured values of plasma concentrations.
Time Frame	Day 14 and Day 28 (end of first two cross-over periods) before drug administration and at 30 min, 1 hour, 1.5, 2, 3, 4, 5, 6, 8, 10, and 12 hours after drug administration

Analysis Population Description

PK population. Two participants were excluded from the PK population: one dropped out of the study during the first period so had no PK samples. The other was omitted due to protocol violations.

Reporting Groups

	Description
CellCept	Timeframes in periods I and II when participants took CellCept in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Timeframes in periods I and II when participants took Myfenax in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Measured Values

	CellCept	Myfenax
Overall Number of Participants Analyzed	41	41

	CellCept	Myfenax
Maximum Observed Plasma Concentration (Cmax) of Mycophenolate Mofetil Mean (Standard Deviation) Unit of measure: µg /ml	16.189 (9.9448)	14.308 (8.3432)

Statistical Analysis 1 for Maximum Observed Plasma Concentration (Cmax) of Mycophenolate Mofetil

Statistical Analysis Overview	Comparison Group Selection	CellCept, Myfenax
	Comments	[Not specified]
	Type of Statistical Test	Non-Inferiority or Equivalence (legacy)
	Comments	Bioequivalence was accepted if the calculated 90 % CIs were within 0.80-1.25.

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [adjusted least-squares mean ratio]
	Estimated Value	0.873
	Confidence Interval	(2-Sided) 90% 0.787 to 0.968
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Minimum Observed Plasma Concentration (Cmin) of Mycophenolate Mofetil
Measure Description	Cmin was directly obtained from measured values of plasma concentrations.
Time Frame	Day 14 and Day 28 (end of first two cross-over periods) before drug administration and at 30 min, 1 hour, 1.5, 2, 3, 4, 5, 6, 8, 10, and 12 hours after drug administration

Analysis Population Description

PK population. Two participants were excluded from the PK population: one dropped out of the study during the first period so had no PK samples. The other was omitted due to protocol violations.

Reporting Groups

	Description
CellCept	Timeframes in periods I and II when participants took CellCept in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Timeframes in periods I and II when participants took Myfenax in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Measured Values

	CellCept	Myfenax
Overall Number of Participants Analyzed	41	41
Minimum Observed Plasma Concentration (Cmin) of Mycophenolate Mofetil Mean (Standard Deviation) Unit of measure: µg /ml	1.584 (0.7801)	1.567 (0.7387)

Statistical Analysis 1 for Minimum Observed Plasma Concentration (Cmin) of Mycophenolate Mofetil

Statistical Analysis Overview	Comparison Group Selection	CellCept, Myfenax
	Comments	[Not specified]
	Type of Statistical Test	Non-Inferiority or Equivalence (legacy)
	Comments	Bioequivalence was accepted if the calculated 90 % CIs were within 0.80-1.25.

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [adjusted least-squares mean ratio]
	Estimated Value	0.985
	Confidence Interval	(2-Sided) 90% 0.877 to 1.106
	Estimation Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Plasma Concentrations of Mycophenolate Mofetil in Pre-Administration Samples (Cpd)
Measure Description	Cpd was directly obtained from measured values of plasma concentrations.
Time Frame	Day 14 and Day 28 (end of first two cross-over periods) before drug administration

Analysis Population Description

PK population. Two participants were excluded from the PK population: one dropped out of the study during the first period so had no PK samples. The other was omitted due to protocol violations.

Reporting Groups

	Description
CellCept	Timeframes in periods I and II when participants took CellCept in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Timeframes in periods I and II when participants took Myfenax in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Measured Values

	CellCept	Myfenax
Overall Number of Participants Analyzed	41	41
Plasma Concentrations of Mycophenolate Mofetil in Pre-Administration Samples (Cpd) Mean (Standard Deviation) Unit of measure: µg /ml	2.693 (1.7001)	3.001 (2.0863)

6. Secondary Outcome Measure:

Measure Title	Degree of Fluctuation of the Concentration Levels of Mycophenolate Mofetil Over One Dosing Interval (PTF)
Measure Description	PTF was calculated as: (Cmax-Cmin)/(AUCt/t)*100
Time Frame	Day 14 and Day 28 (end of first two cross-over periods) before drug administration

Analysis Population Description

PK population. Two participants were excluded from the PK population: one dropped out of the study during the first period so had no PK samples. The other was omitted due to protocol violations.

Reporting Groups

	Description
CellCept	Timeframes in periods I and II when participants took CellCept in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Timeframes in periods I and II when participants took Myfenax in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Measured Values

	CellCept	Myfenax
Overall Number of Participants Analyzed	41	41
Degree of Fluctuation of the Concentration Levels of Mycophenolate Mofetil Over One Dosing Interval (PTF) Mean (Standard Deviation) Unit of measure: percentage of AUC for a dosing interval	351.05 (161.195)	323.67 (156.018)

7. Secondary Outcome Measure:

Measure Title	Time Corresponding to Occurrence of Cmax (Tmax) of Mycophenolate Mofetil
Measure Description	Tmax was directly obtained from measured values.
Time Frame	Day 14 and Day 28 (end of first two cross-over periods) before drug administration

Analysis Population Description

PK population. Two participants were excluded from the PK population: one dropped out of the study during the first period so had no PK samples. The other was omitted due to protocol violations.

Reporting Groups

	Description
CellCept	Timeframes in periods I and II when participants took CellCept in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Timeframes in periods I and II when participants took Myfenax in this cross-over study. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.

Measured Values

	CellCept	Myfenax
Overall Number of Participants Analyzed	41	41
Time Corresponding to Occurrence of Cmax (Tmax) of Mycophenolate Mofetil Mean (Standard Deviation) Unit of measure: hours	1.119 (0.7462)	1.344 (1.1439)

8. Secondary Outcome Measure:

Measure Title	Summary of Participants With Adverse Events
Measure Description	Summary of adverse events across three study time periods. The on-treatment time frame spanned the time during which study drug was administered. Relation to study drug was assessed by the investigator. The Adverse Event count includes serious and non-serious AEs. A serious AE (SAE) was any event that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity or congenital anomaly/birth defect or was an important medical event could have jeopardized the patient's safety or required medical or surgical intervention to prevent one of the outcomes listed above. Severity was measured on a three-point scale: mild, moderate, severe.
Time Frame	Day 1 up to Day 112

Analysis Population Description

Safety population. One participant discontinued the study prior to Period II so the Myfenax # participants analyzed is one less than the CellCept arm.

Reporting Groups

	Description
CellCept	Participants experience while on CellCept during any of the three study periods. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Participants experience while on Myfenax during any of the three study periods. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Overall	Participant experience overall, i.e. all treatment experiences while on study are included

Measured Values

	CellCept	Myfenax	Overall
Overall Number of Participants Analyzed	43	42	43

	CellCept	Myfenax	Overall
Summary of Participants With Adverse Events Measure Type: Number Unit of measure: participants			
Adverse Events	15	17	26
Related adverse events	3	7	9
Severe adverse events	0	0	0
Adverse events leading to discontinuation	2	1	3
Serious adverse events	1	1	1
Adverse events leading to death	0	0	0

Reported Adverse Events

Time Frame	Day 1 up to Day 112
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
CellCept	Participants experience while on CellCept during any of the three study periods. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Myfenax	Participants experience while on Myfenax during any of the three study periods. Doses of mycophenolate mofetil were at least 500 mg twice daily, morning and evening.
Overall	Participant experience overall, i.e. all treatment experiences while on study are included

All-Cause Mortality

	CellCept	Myfenax	Overall
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/	/

Serious Adverse Events

	CellCept	Myfenax	Overall
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/43 (2.33%)	1/42 (2.38%)	1/43 (2.33%)
Cardiac disorders			
Atrial fibrillation [A] †	1/43 (2.33%)	1/42 (2.38%)	1/43 (2.33%)
Cardiac failure [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	CellCept	Myfenax	Overall
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	15/43 (34.88%)	16/42 (38.1%)	26/43 (60.47%)
Blood and lymphatic system disorders			
Lymphadenopathy [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Ear and labyrinth disorders			
Vertigo [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Eye disorders			
Conjunctivitis allergic [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Gastrointestinal disorders			
Abdominal distension [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Abdominal pain [A] †	1/43 (2.33%)	2/42 (4.76%)	3/43 (6.98%)
Diarrhoea [A] †	2/43 (4.65%)	5/42 (11.9%)	6/43 (13.95%)
Dry mouth [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Nausea [A] †	0/43 (0%)	2/42 (4.76%)	2/43 (4.65%)
Periodontitis [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)

	CellCept	Myfenax	Overall
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Rectal discharge [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Vomiting [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
General disorders			
Application site erythema [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Chills [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Oedema peripheral [A] †	2/43 (4.65%)	0/42 (0%)	2/43 (4.65%)
Infections and infestations			
Bronchitis [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Herpes simplex [A] †	2/43 (4.65%)	0/42 (0%)	2/43 (4.65%)
Herpes zoster [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Lower respiratory tract infection [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Nasopharyngitis [A] †	2/43 (4.65%)	0/42 (0%)	2/43 (4.65%)
Rhinitis [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Upper respiratory tract infection [A] †	0/43 (0%)	2/42 (4.76%)	2/43 (4.65%)
Urinary tract infection [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Injury, poisoning and procedural complications			
Arthropod bite [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Joint injury [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Ulna fracture [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Investigations			
Blood pressure increased [A] †	2/43 (4.65%)	0/42 (0%)	2/43 (4.65%)
Blood triglycerides increased [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Cardiac murmur [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)

	CellCept	Myfenax	Overall
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Metabolism and nutrition disorders			
Hyponatraemia [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	0/43 (0%)	2/42 (4.76%)	2/43 (4.65%)
Back pain [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Intervertebral disc protrusion [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Musculoskeletal stiffness [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bowenoid papulosis [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Nervous system disorders			
Headache [A] †	1/43 (2.33%)	3/42 (7.14%)	3/43 (6.98%)
Tremor [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Psychiatric disorders			
Depression [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Respiratory, thoracic and mediastinal disorders			
Cough [A] †	2/43 (4.65%)	0/42 (0%)	2/43 (4.65%)
Skin and subcutaneous tissue disorders			
Onychoclasis [A] †	1/43 (2.33%)	0/42 (0%)	1/43 (2.33%)
Rash [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)
Vascular disorders			
Hypertension [A] †	0/43 (0%)	1/42 (2.38%)	1/43 (2.33%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Limitations and Caveats

The study was designed to have a power of at least 80 % to show bioequivalence with 80 subjects. Only 43 subjects were included.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Sponsor has the right 60 days before submission for publication to review/provide comments. If the Sponsor’s review shows that potentially patentable subject matter would be disclosed, publication or public disclosure shall be delayed for up to 90 additional days in order for the Sponsor, or Sponsor’s designees, to file the necessary patent applications. In multicenter trials, each PI will postpone single center publications until after disclosure or publication of multicenter data.

Results Point of Contact:

Name/Official Title: Director, Clinical Research

Organization: Teva Branded Pharmaceutical Products, R&D Inc.

[redacted]