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Trial record **1 of 1** for: CERL080A2420

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Efficacy and Safety of Enteric-coated Mycophenolate Sodium in Combination With Two Corticosteroid Regimens for the Treatment of Lupus Nephritis Flare

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00423098

First received: January 16, 2007
Last updated: May 31, 2011
Last verified: May 2011
History of Changes

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Results First Received: December 14, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Lupus Nephritis
Interventions:	Drug: Mycophenolate sodium Drug: Prednisone Drug: Methylprednisolone

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

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

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration

	was 24 weeks.

Participant Flow: Overall Study

	Standard Dose	Low Dose
STARTED	42 [1]	39
COMPLETED	39 [2]	35
NOT COMPLETED	3	4
Adverse Event	1	2
Unsatisfactory therapeutic effect	0	1
Administrative problems	0	1
Death	2	0

[1] Total number of patients screened was 90, but the total number of randomized patients was 81.
[2] Completed 24 weeks of study medication.

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
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Total	Total of all reporting groups

Baseline Measures

	Standard Dose	Low Dose	Total
Number of Participants [units: participants]	42	39	81
Age [units: years] Mean (Standard Deviation)	32.2 (8.53)	34.2 (10.74)	33.1 (9.65)
Age, Customized [units: participants]			
18-29 years	20	18	38
30-39 years	16	10	26
40-49 years	4	6	10

50-59 years	**2**	**4**	**6**
>=60 years	**0**	**1**	**1**
Gender [units: participants]			
Female	**37**	**29**	**66**
Male	**5**	**10**	**15**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Patients With Complete Remission [Time Frame: 24 Weeks]

Measure Type	Primary
Measure Title	Number of Patients With Complete Remission
Measure Description	Complete remission was defined as urine protein/urine creatinine ratio < 0.5 gram urine protein per gram urine creatinine, urine sediment normalized (no cellular casts, < 5 red cells per high power field), and serum creatinine within 10% of normal range according to local lab.
Time Frame	24 Weeks
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.
Intention to treat (ITT) population: All randomized patients who received at least one dose of study drug.

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	**Low Dose**
Number of Participants Analyzed [units: participants]	**42**	**39**
Number of Patients With Complete Remission [units: Participants]		
Yes	**8**	**8**
No	**34**	**31**

No statistical analysis provided for Number of Patients With Complete Remission

2. Secondary: Number of Patients With Complete Remission [Time Frame: 12 Weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Complete Remission
Measure Description	Complete remission was defined as urine protein/urine creatinine ratio < 0.5 gram urine protein per gram urine creatinine, urine sediment normalized (no cellular casts, < 5 red cells per high power field), and serum creatinine within 10% of normal value.
Time Frame	12 Weeks
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.
Intention to treat (ITT) population: All randomized patients who received at least one dose of study drug.

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	**Low Dose**
Number of Participants Analyzed [units: participants]	**42**	**39**
Number of Patients With Complete Remission [units: participants]		
Yes	**9**	**5**
No	**33**	**34**

No statistical analysis provided for Number of Patients With Complete Remission

3. Secondary: Number of Patients With Partial Remission [Time Frame: Baseline to 12 and 24 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Partial Remission
Measure Description	Partial remission was defined as urine protein/creatinine ratio reduced by at least 50% from baseline and stable serum creatinine within 10% of baseline value) or improved.
Time Frame	Baseline to 12 and 24 weeks
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.
Intention to treat (ITT) population: All randomized patients who received at least one dose of study drug.

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	**Low Dose**
Number of Participants Analyzed [units: participants]	**42**	**39**
Number of Patients With Partial Remission [units: Participants]		
At 12 weeks - Yes	**16**	**11**
At 12 weeks - No	**26**	**28**
At 24 weeks - Yes	**20**	**14**
At 24 weeks - No	**22**	**25**

No statistical analysis provided for Number of Patients With Partial Remission

4. Secondary: Cumulative Dose of Prednisone Equivalent Corticosteroids (CS) [Time Frame: 12 Weeks and 24 Weeks]

Measure Type	Secondary
Measure Title	Cumulative Dose of Prednisone Equivalent Corticosteroids (CS)
Measure Description	Corticosteroid use was measured as cumulative dose until 12 and 24 weeks of treatment as well as daily doses at baseline, 12 and 24 weeks.
Time Frame	12 Weeks and 24 Weeks
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.
Intention to treat (ITT) population: All randomized patients who received at least one dose of study drug.

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of

	1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	Low Dose
Number of Participants Analyzed [units: participants]	**42**	**39**
Cumulative Dose of Prednisone Equivalent Corticosteroids (CS) [units: mg/kg] Mean (Standard Deviation)		
Week 12	**106.1 (13.55)**	**68.2 (16.41)**
Week 24	**114.2 (15.01)**	**73.0 (17.76)**

No statistical analysis provided for Cumulative Dose of Prednisone Equivalent Corticosteroids (CS)

5. Secondary: Number of Patients With Moderate to Severe Flares [Time Frame: 12 and 24 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Moderate to Severe Flares
Measure Description	A moderate to severe flare was defined as the occurrence of increased lupus activity after partial or complete remission, based on the presence of 1 BILAG A score or >=3 BILAG B scores. British Isles Lupus Assessment Group (BILAG) index divides lupus activity in 8 organs/systems which are each given a score of A to E. A=disease sufficiently active to need disease modifying treatment; B=problems requiring symptomatic treatment; C=mild stable disease; D=previously affected but currently inactive system; E=the system or organ has never been involved. BILAG score: A=9, B=3, C=1, D/E=0; range(0-72)
Time Frame	12 and 24 weeks
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.
Intention to treat (ITT) population: All randomized patients who received at least one dose of study drug.

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	Low Dose
Number of Participants Analyzed [units: participants]	**42**	**39**
Number of Patients With Moderate to Severe Flares [units: participants]		
At week 12 - Yes	**0**	**0**
At week 12 - No	**42**	**39**
At week 24 - Yes	**1**	**0**
At week 24 - No	**41**	**39**

No statistical analysis provided for Number of Patients With Moderate to Severe Flares

6. Secondary: Duration of Exposure to Study Medication [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Duration of Exposure to Study Medication
Measure Description	The duration of exposure was calculated as the date of the last Mycophenolate sodium dose minus the date of the last Mycophenolate sodium dose +1.
Time Frame	24 weeks
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	Low Dose
Number of Participants Analyzed [units: participants]	**42**	**39**
Duration of Exposure to Study Medication [units: days] Mean (Standard Deviation)	**164.5 (24.87)**	**157.7 (41.15)**

No statistical analysis provided for Duration of Exposure to Study Medication

7. Secondary: Number of Patients With Adverse Events and Infections [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Adverse Events and Infections
Measure Description	Safety assessments included collecting all adverse events (AEs), serious adverse events (SAEs), with their severity and relationship to study drug. According to FDA 21CFR 314.80, a serious adverse event (SAE) is described as any adverse event that leads to death, is life threatening (NIH criteria Grade 4), causes or prolongs hospitalization, results in a congenital anomaly, or any other important medical event not described above.
Time Frame	24 weeks
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	Low Dose
Number of Participants Analyzed [units: participants]	**42**	**39**
Number of Patients With Adverse Events and Infections [units: participants]		
At least one adverse event	**35**	**30**
Any severe adverse event	**7**	**3**
Any drug related adverse event	**18**	**16**
Any serious adverse event	**8**	**4**
Any infection	**25**	**17**
Any severe infection	**3**	**1**
Any drug related infection	**10**	**6**
Any serious infection	**4**	**1**

No statistical analysis provided for Number of Patients With Adverse Events and Infections

8. Secondary: Number of Patients With Treatment Failure [Time Frame: 12 Weeks and 24 Weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Treatment Failure
Measure Description	Treatment failure was defined as no therapeutic response (without complete or partial remission) or premature discontinuation during the first 24 weeks from study medication or the study for any reason except complete or partial remission.
Time Frame	12 Weeks and 24 Weeks
Safety Issue	Yes

Population Description

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

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	**Low Dose**
Number of Participants Analyzed [units: participants]	**42**	**39**
Number of Patients With Treatment Failure [units: participants]		
At 12 weeks - Yes	**23**	**25**
At 12 weeks - No	**19**	**14**
At 24 weeks - Yes	**21**	**22**
At 24 weeks - No	**21**	**17**

No statistical analysis provided for Number of Patients With Treatment Failure

9. Secondary: Change From Baseline in Overall Disease Activity With Systematic Lupus Erythematosus Disease Activity Index (SLEDAI) [Time Frame: From Baseline to week 4, week 12 and week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Overall Disease Activity With Systematic Lupus Erythematosus Disease Activity Index (SLEDAI)
Measure Description	SLEDAI stands for Systemic Lupus Erythematosus Disease Activity Index and was a well established global score index based on assessment of 24 items measuring a disease activity in the 10-day period prior to the assessment. SLEDAI item weights range from 1 for fever to 8 for seizures. A maximum theoretical score is 105. Total score range

	from 1 to 105. A flare has been defined as a SLEDAI score increase of 3 or more to a level of 8 or higher. During flares SLEDAI scores of 25 to 30 are common.
Time Frame	From Baseline to week 4, week 12 and week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population included all randomized patients who received at least one dose of study drug. Only patients with assessments at both baseline and post-baseline visits are summarized.

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	**Low Dose**
Number of Participants Analyzed [units: participants]	**42**	**39**
Change From Baseline in Overall Disease Activity With Systematic Lupus Erythematosus Disease Activity Index (SLEDAI) [units: Units on a scale] Mean (Standard Deviation)		
Change from Baseline to Week 4: (N= 39, 37)	**-7.4 (5.63)**	**-7.7 (6.62)**
Change from Baseline to Week 12: (N= 41, 35)	**-9.7 (7.08)**	**-10.3 (8.31)**
Change from Baseline to Week 24: (N= 39, 34)	**-10.3 (7.32)**	**-9.8 (8.35)**

No statistical analysis provided for Change From Baseline in Overall Disease Activity With Systematic Lupus Erythematosus Disease Activity Index (SLEDAI)

10. Secondary: Change From Baseline in Overall Disease Activity With British Isles Lupus Assessment Group (BILAG) [Time Frame: From Baseline to week 4, week 12 and week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Overall Disease Activity With British Isles Lupus Assessment Group (BILAG)
Measure Description	BILAG (British Isles Lupus Assessment Group) index divides lupus activity into 8 organs/systems and was based on the principle of the physician's intention to treat, assessing activity in the previous one month. Each organ or system was given a score of A to E, where A = disease that is sufficiently active to require disease modifying treatment; a B = problems requiring symptomatic treatment; C = stable mild disease; D = previously affected but currently inactive system; and E = the system or organ has never been involved. [A=9, B=3, C=1, D/E=0 the score range for each

	patient will be 0-72].
Time Frame	From Baseline to week 4, week 12 and week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) populationincluded all randomized patients who received at least one dose of study drug. Only patients with assessments at both baseline and post-baseline visits are summarized.

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Measured Values

	Standard Dose	Low Dose
Number of Participants Analyzed [units: participants]	**42**	**39**
Change From Baseline in Overall Disease Activity With British Isles Lupus Assessment Group (BILAG) [units: Units on a scale] Mean (Standard Deviation)		
Change from baseline Week 4: (N= 40, 37)	**-4.8 (5.34)**	**-5.5 (6.50)**
Change from baseline Week 12: (N= 41, 35)	**-8.6 (6.76)**	**-8.7 (6.19)**
Change from baseline Week 24: (N= 40, 34)	**-8.6 (5.79)**	**-9.4 (5.52)**

No statistical analysis provided for Change From Baseline in Overall Disease Activity With British Isles Lupus Assessment Group (BILAG)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as

	prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Serious Adverse Events

	Standard Dose	Low Dose
Total, serious adverse events		
# participants affected / at risk	**8/42 (19.05%)**	**4/39 (10.26%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Pancreatitis acute † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Vomiting † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
General disorders		
Death † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Mucosal inflammation † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Multi-organ failure † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Oedema peripheral † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Infections and infestations		
Cytomegalovirus infection † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Epstein-barr virus infection † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Gastroenteritis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/39 (2.56%)**
Herpes zoster † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Sinusitis † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Injury, poisoning and procedural complications		
Fall † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/39 (2.56%)**
Tendon rupture † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/39 (2.56%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**0/42 (0.00%)**	**1/39 (2.56%)**
Syncope † 1		

# participants affected / at risk	**0/42 (0.00%)**	**1/39 (2.56%)**
Renal and urinary disorders		
Renal failure acute † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Dysphonia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**0/39 (0.00%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**1/42 (2.38%)**	**1/39 (2.56%)**

† 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
Standard Dose	Mycophenolate sodium was administered orally in combination with a standard dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 1 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.
Low Dose	Mycophenolate sodium was administered orally in combination with a reduced dose of corticosteroids (CS) administered as prednisone or prednisone equivalent (PRED). Mycophenolate sodium was administered in divided doses at a daily dose of 1440 mg during the first 2 weeks of the study and then at 2160 mg daily for the next 22 weeks. The dose of CS was started at 0.5 mg per kg body weight and subsequently tapered according to the patient's weight. The planned treatment duration was 24 weeks.

Other Adverse Events

	Standard Dose	**Low Dose**
Total, other (not including serious) adverse events		
# participants affected / at risk	**28/42 (66.67%)**	**18/39 (46.15%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**3/39 (7.69%)**
Cardiac disorders		
Tachycardia † 1		
# participants affected / at risk	**1/42 (2.38%)**	**2/39 (5.13%)**
Gastrointestinal disorders		

Abdominal pain upper † 1		
# participants affected / at risk	**1/42 (2.38%)**	**3/39 (7.69%)**
Constipation † 1		
# participants affected / at risk	**3/42 (7.14%)**	**1/39 (2.56%)**
Diarrhoea † 1		
# participants affected / at risk	**9/42 (21.43%)**	**8/39 (20.51%)**
Gastritis † 1		
# participants affected / at risk	**0/42 (0.00%)**	**2/39 (5.13%)**
Nausea † 1		
# participants affected / at risk	**3/42 (7.14%)**	**1/39 (2.56%)**
Vomiting † 1		
# participants affected / at risk	**3/42 (7.14%)**	**4/39 (10.26%)**
General disorders		
Oedema peripheral † 1		
# participants affected / at risk	**4/42 (9.52%)**	**5/39 (12.82%)**
Infections and infestations		
Folliculitis † 1		
# participants affected / at risk	**0/42 (0.00%)**	**2/39 (5.13%)**
Herpes zoster † 1		
# participants affected / at risk	**6/42 (14.29%)**	**0/39 (0.00%)**
Nasopharyngitis † 1		
# participants affected / at risk	**4/42 (9.52%)**	**1/39 (2.56%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**4/42 (9.52%)**	**2/39 (5.13%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**4/42 (9.52%)**	**5/39 (12.82%)**
Muscle spasms † 1		
# participants affected / at risk	**3/42 (7.14%)**	**1/39 (2.56%)**
Musculoskeletal stiffness † 1		
# participants affected / at risk	**0/42 (0.00%)**	**2/39 (5.13%)**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**4/42 (9.52%)**	**4/39 (10.26%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**3/42 (7.14%)**	**2/39 (5.13%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**2/42 (4.76%)**	**2/39 (5.13%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

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

Results Point of Contact:

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

No publications provided

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00423098 History of Changes
Other Study ID Numbers:	**CERL080A2420**
Study First Received:	January 16, 2007
Results First Received:	December 14, 2010
Last Updated:	May 31, 2011
Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)