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Trial record **1 of 1** for: COLO400CIT04

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Efficacy and Safety of Cyclosporine A Microemulsion in Maintenance Patients With Chronic Plaque Psoriasis

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00438360

First received: February 21, 2007
Last updated: July 13, 2011
Last verified: July 2011
History of Changes

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

Results First Received: December 15, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Chronic Plaque Psoriasis
Interventions:	Drug: Cyclosporine A microemulsion Drug: Placebo

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
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Participant Flow: Overall Study

	Cyclosporine A	**Placebo**
STARTED	**162** [1]	**81**

Intention to Treat (ITT) Population	**160** [2]	**79**
COMPLETED	**90**	**38**
NOT COMPLETED	**72**	**43**
Adverse Event	**6**	**1**
Lack of Efficacy	**42**	**27**
not specified	**24**	**15**

[1] "Started" indicates randomized patients.
[2] These numbers are different from those started (randomized) as 2 pts from each arm never took drug.

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
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.
Total	Total of all reporting groups

Baseline Measures

	Cyclosporine A	Placebo	Total
Number of Participants [units: participants]	**160**	**79**	**239**
Age, Customized [1] **[units: Participants]**			
between 18-45 years	**100**	**48**	**148**
Between 46 and 65 years	**59**	**29**	**88**
>=65 years	**1**	**2**	**3**
Gender [units: participants]			
Female	**55**	**32**	**87**
Male	**105**	**47**	**152**

[1] Baseline measures are based on intention to treat (ITT) population.

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Relapse Rate (Success or Failure), as Assessed by Psoriasis Area and Severity Index (PASI) Score [Time Frame: 24 weeks]

Measure Type	Primary
Measure Title	Number of Participants With Relapse Rate (Success or Failure), as Assessed by Psoriasis Area and Severity Index (PASI) Score
Measure Description	PASI is an index used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (best) to 72 (worst), with the highest score representing complete erythroderma of severest degree. Relapse is considered a worsening of psoriasis associated to a PASI score >75% of PASI score recorded before starting induction therapy with CsA (before study start). Each patient was considered as failure (relapse occurrence) if rate was >= 75%. In all the other cases the patient was considered as success (no relapse).
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.
Intent to treat population.

Reporting Groups

	Description
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Measured Values

	Cyclosporine A	**Placebo**
Number of Participants Analyzed [units: participants]	**160**	**79**
Number of Participants With Relapse Rate (Success or Failure), as Assessed by Psoriasis Area and Severity Index (PASI) Score [units: Participants]		
Success at 6 months	**87**	**36**
Failure at 6 months	**73**	**43**

No statistical analysis provided for Number of Participants With Relapse Rate (Success or Failure), as Assessed by Psoriasis Area and Severity Index (PASI) Score

2. Secondary: Proportion of Participants With Clinical Relapse [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Proportion of Participants With Clinical Relapse
Measure Description	Clinical relapse was defined as worsening of psoriasis associated with a Psoriasis Area and Severity Index (PASI) >75% of the PASI score assessed before the continuous treatment, or when the investigator or the patient judged it necessary to change the treatment.
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.
Intent to treat population.

Reporting Groups

	Description
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Measured Values

	Cyclosporine A	**Placebo**
Number of Participants Analyzed [units: participants]	**160**	**79**
Proportion of Participants With Clinical Relapse [units: proportion of participants]	**0.369**	**0.456**

No statistical analysis provided for Proportion of Participants With Clinical Relapse

3. Secondary: Change From Baseline in Psoriasis Area and Severity Index (PASI) Score [Time Frame: baseline and week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Psoriasis Area and Severity Index (PASI) Score
Measure Description	PASI is an index used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (best) to 72 (worst), with the highest score representing complete erythroderma of the severest degree.
Time Frame	baseline 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.
Intention to treat (ITT) population. Patients with a value of PASI at baseline and 24 weeks were included in this analysis.

Reporting Groups

	Description
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Measured Values

	Cyclosporine A	**Placebo**
Number of Participants Analyzed [units: participants]	**158**	**76**
Change From Baseline in Psoriasis Area and Severity Index (PASI) Score [units: Units on a scale] Mean (Standard Deviation)	**5.70 (8.0)**	**6.86 (8.4)**

No statistical analysis provided for Change From Baseline in Psoriasis Area and Severity Index (PASI) Score

4. Secondary: Change From Baseline in Body Surface Area (BSA) Affected by Psoriasis [Time Frame: Baseline and week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Body Surface Area (BSA) Affected by Psoriasis
Measure Description	BSA is a measure of the percentage of body surface affected by psoriasis. Using the Mosteller Formula: BSA = BSA (m^2) = ([Height(in) x Weight(lbs)]/ 3131)½ . A covariance analysis was performed on all variables, with value assessed at visit 2 as covariate and center as effect. For each variable the changes versus the last available measures were computed
Time Frame	Baseline 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. Patients with a value of BSA at baseline and 24 weeks were included in this analysis.

Reporting Groups

	Description
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Measured Values

	Cyclosporine A	**Placebo**
Number of Participants Analyzed [units: participants]	**158**	**76**
Change From Baseline in Body Surface Area (BSA) Affected by Psoriasis [units: BSA (m^2)] Mean (Standard Deviation)	**8.12 (12.9)**	**10.45 (16.7)**

No statistical analysis provided for Change From Baseline in Body Surface Area (BSA) Affected by Psoriasis

5. Secondary: Change From Baseline in Visual Analogue Scale (VAS) for Patient Self Assessment of Pruritus [Time Frame: Baseline and week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Visual Analogue Scale (VAS) for Patient Self Assessment of Pruritus
Measure Description	Target lesion pruritus as measured by the Visual Analog Scale (VAS) from 0 to 100 mm at week 24 compared to baseline (with 0 being no pruritis and 100 being maximum pruritis).
Time Frame	Baseline 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. Patients with a value of VAS at baseline and 24 weeks were included in this analysis.

Reporting Groups

	Description
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Measured Values

	Cyclosporine A	Placebo
Number of Participants Analyzed [units: participants]	**158**	**76**
Change From Baseline in Visual Analogue Scale (VAS) for Patient Self Assessment of Pruritus [units: Units on a scale] Mean (Standard Deviation)	**17.32 (30.9)**	**25.44 (31.9)**

No statistical analysis provided for Change From Baseline in Visual Analogue Scale (VAS) for Patient Self Assessment of Pruritus

6. Secondary: Safety / Tolerability Assessed by Adverse Events [Time Frame: 24weeks]

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	24 weeks
Additional Description	Safety Population

Reporting Groups

	Description
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Serious Adverse Events

	Cyclosporine A	Placebo
Total, serious adverse events		
# participants affected / at risk	**1/160 (0.63%)**	**0/79 (0.00%)**
Reproductive system and breast disorders		
Breast mass † 1		
# participants affected / at risk	**1/160 (0.63%)**	**0/79 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	24 weeks
Additional Description	Safety Population

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Cyclosporine A	Oral soft gelatin capsules of cyclosporine 10 mg, 25 mg, 50 mg or 100 mg administered twice a week for 24 weeks at the dosage of 5 mg/Kg/day in two daily administrations.
Placebo	Oral soft gelatin capsules of placebo matching cyclosporine administered twice a week for 24 weeks in two daily administrations.

Other Adverse Events

	Cyclosporine A	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**19/160 (11.88%)**	**1/79 (1.27%)**
Gastrointestinal disorders		
Abdominal pain upper † 1		
# participants affected / at risk	**12/160 (7.50%)**	**1/79 (1.27%)**
Metabolism and nutrition disorders		
Hypertriglyceridaemia † 1		
# participants affected / at risk	**8/160 (5.00%)**	**0/79 (0.00%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can

☐ embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

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:	NCT00438360 History of Changes
Other Study ID Numbers:	**COLO400CIT04**
Study First Received:	February 21, 2007
Results First Received:	December 15, 2010
Last Updated:	July 13, 2011
Health Authority:	Italy: The Italian Medicines Agency