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Trial record **1 of 1** for: CELC200AES03

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Efficacy of Levodopa/Carbidopa/Entacapone vs Levodopa/Carbidopa in Parkinson's Disease Patients With Early Wearing-off

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00391898

First received: October 24, 2006
Last updated: February 16, 2011
Last verified: February 2011
History of Changes

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

Results First Received: January 4, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Parkinson's Disease
Interventions:	Drug: Levodopa/carbidopa/entacapone Drug: Levodopa/carbidopa

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
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Participant Flow: Overall Study

	Levodopa/Carbidopa/Entacapone	Levodopa/Carbidopa
STARTED	**46** [1]	**49**
COMPLETED	**35**	**39**
NOT COMPLETED	**11**	**10**
Adverse Event	**3**	**0**
Other	**8**	**10**

[1] Safety population for Levodopa/carbidopa/entacapone is 45, for Levodopa/carbidopa, per randomized.

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
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.
Total	Total of all reporting groups

Baseline Measures

	Levodopa/Carbidopa/Entacapone	**Levodopa/Carbidopa**	**Total**
Number of Participants [units: participants]	**45**	**49**	**94**
Age [units: Years] Mean (Standard Deviation)	**66.40 (8.18)**	**66.45 (9.04)**	**66.43 (8.59)**
Gender [1] **[units: participants]**			
Female	**25**	**22**	**47**
Male	**20**	**27**	**47**

Region of Enrollment [2] [units: participants]			
Spain	45	49	94

[1] Baseline Measure based on Safety population
[2] Baseline measure based on safety population.

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in the Unified Parkinson's Disease Rating Scale (UPDRS) Part II (Activities of Daily Living [ADL]) Score From Baseline to Month 3 [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Primary
Measure Title	Change in the Unified Parkinson's Disease Rating Scale (UPDRS) Part II (Activities of Daily Living [ADL]) Score From Baseline to Month 3
Measure Description	The UPDRS is a standardized assessment scale used to measure a patient's disease state. It is completed by a blinded rater. There are 6 parts to the UPDRS. Part II (items 5-17; total score 0-52, calculated as the sum of the individual items) measures the patient's activities of daily living. A lower total score indicates greater symptom control. A negative change score indicates improvement.
Time Frame	Baseline to end of study (Month 3)
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.
Per Protocol set with the last observation carried forward (LOCF)

Reporting Groups

	Description

Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Measured Values

	Levodopa/Carbidopa/Entacapone	**Levodopa/Carbidopa**
Number of Participants Analyzed **[units: participants]**	**35**	**36**
Change in the Unified Parkinson's Disease Rating Scale (UPDRS) Part II (Activities of Daily Living [ADL]) Score From Baseline to Month 3 **[units: Units on a scale]** **Mean (Standard Deviation)**	**-2.5 (2.8)**	**-0.5 (3.0)**

No statistical analysis provided for Change in the Unified Parkinson's Disease Rating Scale (UPDRS) Part II (Activities of Daily Living [ADL]) Score From Baseline to Month 3

2. Secondary: Change in the UPDRS Part I (Mentation, Behavior, and Mood) Score From Baseline to Month 3 [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary
Measure Title	Change in the UPDRS Part I (Mentation, Behavior, and Mood) Score From Baseline to Month 3
Measure Description	The UPDRS is a standardized assessment scale used to measure a patient's disease state. It is completed by a blinded rater. There are 6 parts to the UPDRS. Part I (items 1-4; total score 0-16, calculated as the sum of the individual items) measures the patient’s mentation, mood and behavior. A lower total score indicates greater symptom control. A negative change score indicates improvement.
Time Frame	Baseline to end of study (Month 3)

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.
Per Protocol set with LOCF

Reporting Groups

	Description
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Measured Values

	Levodopa/Carbidopa/Entacapone	**Levodopa/Carbidopa**
Number of Participants Analyzed [units: participants]	**35**	**36**
Change in the UPDRS Part I (Mentation, Behavior, and Mood) Score From Baseline to Month 3 [units: Units on a scale] Mean (Standard Deviation)	**-0.5 (1.6)**	**-0.2 (1.0)**

No statistical analysis provided for Change in the UPDRS Part I (Mentation, Behavior, and Mood) Score From Baseline to Month 3

3. Secondary: Change in the UPDRS Part III (Motor Function) Score From Baseline to Month 3 [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary
Measure Title	Change in the UPDRS Part III (Motor Function) Score From Baseline to Month 3
Measure Description	The UPDRS is a standardized assessment scale used to measure a patient's disease state. It is completed by a blinded rater. There are 6 parts to the UPDRS. Part III (items 18-31; total score 0-56, calculated as the sum of the individual items) measures the patient's motor function. A lower total score indicates greater symptom control. A negative change score indicates improvement.
Time Frame	Baseline to end of study (Month 3)
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.
Per Protocol set with LOCF

Reporting Groups

	Description
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Measured Values

	Levodopa/Carbidopa/Entacapone	**Levodopa/Carbidopa**
Number of Participants Analyzed **[units: participants]**	**35**	**36**
Change in the UPDRS Part III (Motor Function) Score From Baseline to Month 3 **[units: Units on a scale]** **Mean (Standard Deviation)**	**-4.0 (4.6)**	**-1.42 (5.5)**

No statistical analysis provided for Change in the UPDRS Part III (Motor Function) Score From Baseline to Month 3

4. Secondary: Change in the UPDRS Part IV (Complications of Therapy) Score From Baseline to Month 3 [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary
Measure Title	Change in the UPDRS Part IV (Complications of Therapy) Score From Baseline to Month 3
Measure Description	Part IV of the UPDRS measures complications the patient may be experiencing with therapy and was only collected at and after the visit at which the first dyskinesia or episode of wearing-off was recorded. Part IV is composed of 3 sections and 11 items: A (32-35, dyskinesia), B (36-39, clinical fluctuations, C (40-42, other complications) (total score 0-23, calculated as the sum of the individual items). A lower total score indicates greater symptom control. A negative change score indicates improvement.
Time Frame	Baseline to end of study (Month 3)
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.
Per Protocol set with LOCF

Reporting Groups

	Description
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Measured Values

	Levodopa/Carbidopa/Entacapone	Levodopa/Carbidopa
Number of Participants Analyzed **[units: participants]**	**35**	**36**
Change in the UPDRS Part IV (Complications of Therapy) Score From Baseline to Month 3 **[units: Units on a scale]** **Mean (Standard Deviation)**	**-0.6 (1.8)**	**-0.1 (1.3)**

No statistical analysis provided for Change in the UPDRS Part IV (Complications of Therapy) Score From Baseline to Month 3

5. Secondary: Change in the 39-item Parkinson's Disease Questionnaire (PDQ-39) Total Score From Baseline to Month 3 [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary
Measure Title	Change in the 39-item Parkinson's Disease Questionnaire (PDQ-39) Total Score From Baseline to Month 3
Measure Description	The PDQ-39 is an instrument used to assess quality of life in individuals with Parkinson’s disease. The questionnaire provides scores on eight scales: Mobility, activities of daily living, emotions, stigma, social support, cognitions, communication, and bodily discomfort. Questions are scored on a 5-point Likert scale ranging from 1 (never) to 3 (sometimes) to 5 (always). The total score can range from 39 to 195. A lower score indicates better quality of life. A positive change score indicates an improvement.
Time Frame	Baseline to end of study (Month 3)
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.
Per Protocol set with LOCF

Reporting Groups

	Description
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were

	taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Measured Values

	Levodopa/Carbidopa/Entacapone	**Levodopa/Carbidopa**
Number of Participants Analyzed **[units: participants]**	**35**	**36**
Change in the 39-item Parkinson's Disease Questionnaire (PDQ-39) Total Score From Baseline to Month 3 **[units: Units on a scale]** **Mean (Standard Deviation)**	**6.3 (20.4)**	**0.8 (15.6)**

No statistical analysis provided for Change in the 39-item Parkinson's Disease Questionnaire (PDQ-39) Total Score From Baseline to Month 3

6. Secondary: Patient and Investigator Global Evaluation of the Patient [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary
Measure Title	Patient and Investigator Global Evaluation of the Patient
Measure Description	Both the patient and the investigator made an evaluation of the change in the patient's condition by rating the condition of the patient at the end of the study compared to patient's condition at baseline. The rating was made on a scale ranging from -3 to +3: (-3: Very much improved, -2: much improved, -1: mild improvement, 0: no change, +1: mild deterioration, +2: much deterioration, +3: very much deterioration). A negative score indicates improvement.
Time Frame	Baseline to end of study (Month 3)
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.
Per Protocol set with LOCF

Reporting Groups

	Description
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Measured Values

	Levodopa/Carbidopa/Entacapone	**Levodopa/Carbidopa**
Number of Participants Analyzed [units: participants]	**34**	**35**
Patient and Investigator Global Evaluation of the Patient [units: Units on a scale] Mean (Standard Deviation)		
Patient global evaluation	**-0.9 (1.1)**	**-0.4 (1.2)**
Investigator global evaluation	**-0.9 (1.0)**	**-0.3 (0.9)**

No statistical analysis provided for Patient and Investigator Global Evaluation of the Patient

7. Secondary: Change on the QUICK Questionnaire (QQ) Score From Baseline to Month 3 [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary

Measure Title	Change on the QUICK Questionnaire (QQ) Score From Baseline to Month 3
Measure Description	The QQ is a self-administered questionnaire that includes 19 wearing-off (WO) symptoms (motor and non-motor). A positive answer to each of the 19 symptoms is given by patients if they presented with a symptom and the symptom disappeared after the next drug dose. Two positive answers are diagnostic of wearing-off (WO). A negative change score indicates improvement.
Time Frame	Baseline to end of study (Month 3)
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.
Per Protocol set with LOCF

Reporting Groups

	Description
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Measured Values

	Levodopa/Carbidopa/Entacapone	**Levodopa/Carbidopa**
Number of Participants Analyzed **[units: participants]**	**35**	**36**
Change on the QUICK Questionnaire (QQ) Score From Baseline to Month 3 **[units: Positive answers]** **Mean (Standard Deviation)**	**-0.6 (1.8)**	**-0.6 (2.3)**

No statistical analysis provided for Change on the QUICK Questionnaire (QQ) Score From Baseline to Month 3

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Serious Adverse Events

	Levodopa/Carbidopa/Entacapone	Levodopa/Carbidopa
Total, serious adverse events		
# participants affected / at risk	**1/45 (2.22%)**	**1/49 (2.04%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma †1		
# participants affected / at risk	**1/45 (2.22%)**	**0/49 (0.00%)**
Psychiatric disorders		
Delusion †1		
# participants affected / at risk	**0/45 (0.00%)**	**1/49 (2.04%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 13.1

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
Levodopa/Carbidopa/Entacapone	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa/entacapone was available in 2 oral dosage forms: 100/25/200 or 150/37.5/200 mg encapsulated tablets.
Levodopa/Carbidopa	Patients were instructed to take the study medication at the same hours and the same levodopa dose they were taking prior to enrollment in this study. Levodopa/carbidopa was available in 2 oral dosage forms: One or one and one-half 100/25 mg encapsulated tablets.

Other Adverse Events

	Levodopa/Carbidopa/Entacapone	Levodopa/Carbidopa
Total, other (not including serious) adverse events		
# participants affected / at risk	**10/45 (22.22%)**	**3/49 (6.12%)**
Gastrointestinal disorders		
Retching †1		
# participants affected / at risk	**3/45 (6.67%)**	**2/49 (4.08%)**
Nervous system disorders		
Dyskinesia †1		

# participants affected / at risk	**7/45 (15.56%)**	**1/49 (2.04%)**
Psychiatric disorders		
Anxiety †1		
# participants affected / at risk	**5/45 (11.11%)**	**0/49 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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:	NCT00391898 History of Changes
Other Study ID Numbers:	**CELC200AES03**
Study First Received:	October 24, 2006
Results First Received:	January 4, 2011
Last Updated:	February 16, 2011
Health Authority:	Spain: Agencia Española del Medicamento y Productos Sanitarios. Ministerio de Sanidad y Consumo