ClinicalTrials.gov

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

Trial record **1 of 1** for: CENA713DES07

Previous Study | Return to List | Next Study

Convenience, Tolerability, and Safety of Change in the Administration of Rivastigmine From Capsules to a Transdermal Patch in Patients With Mild to Moderate Alzheimer's Disease (KAPA)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00549601

First received: October 24, 2007
Last updated: February 24, 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 5, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Alzheimer's Disease
Interventions:	Drug: Rivastigmine patch (4.6 mg/day switch to 9.5 mg/day) Drug: Rivastigmine patch (9.5 mg/day) Drug: Rivastigmine capsules (6 mg to 12 mg/day)

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
Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Participant Flow for 2 periods

Period 1: Randomized

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine Patch (9.5 mg/Day)	Rivastigmine Capsules (6 mg to 12 mg/Day)
STARTED	**43**	**48**	**51**
COMPLETED	**43**	**47**	**49**
NOT COMPLETED	**0**	**1**	**2**
Protocol Violation	**0**	**0**	**1**
Withdrawal by	**0**	**1**	**1**

Subject			

Period 2: Received Study Drug

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine Patch (9.5 mg/Day)	Rivastigmine Capsules (6 mg to 12 mg/Day)
STARTED	**43** [1]	**47** [1]	**49** [1]
COMPLETED	**36**	**36**	**45**
NOT COMPLETED	**7**	**11**	**4**
Adverse Event	**2**	**5**	**1**
Death	**0**	**1**	**0**
Lost to Follow-up	**0**	**1**	**1**
Protocol Violation	**3**	**4**	**1**
Withdrawal by Subject	**2**	**0**	**1**

[1] Subjects who started this period (safety population) received at least 1 dose of study 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
Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).

Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.
Total	Total of all reporting groups

Baseline Measures

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine Patch (9.5 mg/Day)	Rivastigmine Capsules (6 mg to 12 mg/Day)	Total
Number of Participants [units: participants]	**43**	**47**	**49**	**139**
Age [units: years] Mean (Standard Deviation)	**77.05 (4.82)**	**75.34 (7.25)**	**77.35 (6.62)**	**76.58 (6.37)**
Gender [units: participants]				
Female	**30**	**29**	**25**	**84**
Male	**13**	**18**	**24**	**55**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Patients Who Had a Gastrointestinal Adverse Event (AE) at Any Time During the Study [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Primary
Measure Title	Percentage of Patients Who Had a Gastrointestinal Adverse Event (AE) at Any Time During the Study

Measure Description	Gastrointestinal adverse events (including nausea, vomiting, and diarrhea) were coded using the medical dictionary MedDRA v11.0 and the number of patients who suffered an AE were described by system organ class (SOC) and preferred term (PT).
Time Frame	Baseline to end of study (Month 3)
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.
The Safety population included all randomized patients who received at least one dose of the study medication.

Reporting Groups

	Description
Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Measured Values

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	**Rivastigmine Patch (9.5 mg/Day)**	**Rivastigmine Capsules (6 mg to 12 mg/Day)**
Number of Participants Analyzed **[units: participants]**	**43**	**47**	**49**
Percentage of Patients Who Had a Gastrointestinal Adverse Event (AE) at Any Time During the Study **[units: Percentage of participants]**	**4.65**	**4.26**	**6.12**

No statistical analysis provided for Percentage of Patients Who Had a Gastrointestinal Adverse Event (AE) at Any Time During the Study

2. Secondary: Percentage of Patients With an AE Involving the Skin (Local Tolerance) Recorded Over the Course of the Study Period (Patch Groups Only) [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary
Measure Title	Percentage of Patients With an AE Involving the Skin (Local Tolerance) Recorded Over the Course of the Study Period (Patch Groups Only)
Measure Description	Adverse events involving the skin included urticaria, pruritus, erythema, and pigmentation disorder. Only the groups administered rivastigmine transdermally via patch were analyzed. The adverse events were coded using the medical dictionary MedDRA v11.0 and the number of patients who suffered an AE were described by system organ class (SOC) and preferred term (PT).
Time Frame	Baseline to end of study (Month 3)
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.
The Safety population included all randomized patients who received at least one dose of the study medication.

Reporting Groups

	Description
Rivastigmine 4.6 mg/9.5 mg Patch	Rivastigmine transdermal patches at increasing doses: Application of one 4.6 mg patch every day for the first month of treatment and thereafter daily application of one 9.5 mg patch for the next two months.
Rivastigmine 9.5 mg Patch	Rivastigmine transdermal patches at a constant dose: Application of one 9.5 mg patch every day for the whole treatment period.

Measured Values

	Rivastigmine 4.6 mg/9.5 mg Patch	**Rivastigmine 9.5 mg Patch**
Number of Participants Analyzed [units: participants]	**43**	**47**

Percentage of Patients With an AE Involving the Skin (Local Tolerance) Recorded Over the Course of the Study Period (Patch Groups Only) **[units: Percentage of participants]**	**11.63**	**17.02**

No statistical analysis provided for Percentage of Patients With an AE Involving the Skin (Local Tolerance) Recorded Over the Course of the Study Period (Patch Groups Only)

3. Secondary: Percentage of Patients With at Least 1 AE of Any Kind Recorded During the Period of the Study. [Time Frame: Baseline to end of study (Month 3)]

Measure Type	Secondary
Measure Title	Percentage of Patients With at Least 1 AE of Any Kind Recorded During the Period of the Study.
Measure Description	Adverse events were coded using the medical dictionary MedDRA v11.0 and the number of patients who suffered an AE were described by system organ class (SOC) and preferred term (PT). They were also tabulated by severity, relationship with study treatment, and action taken.
Time Frame	Baseline to end of study (Month 3)
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.
The Safety population included all randomized patients who received at least one dose of the study medication.

Reporting Groups

	Description
Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).

Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Measured Values

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine Patch (9.5 mg/Day)	Rivastigmine Capsules (6 mg to 12 mg/Day)
Number of Participants Analyzed [units: participants]	**43**	**47**	**49**
Percentage of Patients With at Least 1 AE of Any Kind Recorded During the Period of the Study. [units: Percentage of participants]	**48.84**	**55.32**	**53.06**

No statistical analysis provided for Percentage of Patients With at Least 1 AE of Any Kind Recorded During the Period of the Study.

4. Secondary: Overall Caregiver Satisfaction With Treatment [Time Frame: At end of study (Month 3)]

Measure Type	Secondary
Measure Title	Overall Caregiver Satisfaction With Treatment
Measure Description	Caregivers were asked to rate their overall degree of satisfaction with the Alzheimer's disease treatment on a scale of 1 to 5 (1 “Very good” – 5 “Very poor”) at the end of the study (Month 3). A higher score indicates less satisfaction.
Time Frame	At 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.
The Safety population included all randomized patients who received at least one dose of the study medication.

Reporting Groups

	Description
Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Measured Values

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine Patch (9.5 mg/Day)	Rivastigmine Capsules (6 mg to 12 mg/Day)
Number of Participants Analyzed [units: participants]	**43**	**47**	**49**
Overall Caregiver Satisfaction With Treatment [units: Participants]			
Not Decided (ND)	**1**	**3**	**1**
Very good	**18**	**20**	**10**
Good	**18**	**14**	**33**
Average	**3**	**5**	**2**
Poor	**3**	**2**	**3**
Very Poor	**0**	**3**	**0**

No statistical analysis provided for Overall Caregiver Satisfaction With Treatment

5. Secondary: Overall Patient Satisfaction With Treatment [Time Frame: At end of study (Month 3)]

Measure Type	Secondary

Measure Title	Overall Patient Satisfaction With Treatment
Measure Description	Patients were asked to rate their overall degree of satisfaction with the Alzheimer's disease treatment on a scale of 1 to 5 (1 “Very good” - 5 “Very poor”) at the end of the study (Month 3). A higher score indicates less satisfaction.
Time Frame	At 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.
The Safety population included all randomized patients who received at least one dose of the study medication.

Reporting Groups

	Description
Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Measured Values

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	**Rivastigmine Patch (9.5 mg/Day)**	**Rivastigmine Capsules (6 mg to 12 mg/Day)**
Number of Participants Analyzed **[units: participants]**	**43**	**47**	**49**
Overall Patient Satisfaction With Treatment **[units: Participants]**			
Not Decided (ND)	**0**	**3**	**1**

Very good	**18**	**14**	**12**
Good	**20**	**21**	**29**
Average	**3**	**6**	**5**
Poor	**2**	**2**	**2**
Very Poor	**0**	**1**	**0**

No statistical analysis provided for Overall Patient Satisfaction With Treatment

6. Secondary: Change in the Total Mini-Mental State Examination (MMSE) Score From Baseline to Month 1 and Month 3 [Time Frame: Baseline to Month 1 and Month 3]

Measure Type	Secondary
Measure Title	Change in the Total Mini-Mental State Examination (MMSE) Score From Baseline to Month 1 and Month 3
Measure Description	The Mini Mental State Examination (MMSE) was used to evaluate the patient's cognitive status and how it progressed over time. The 35-point version used in this study was made up of five sections: orientation, fixation, attention and calculation, memory and language, and constructional praxis. The total score for each patient was obtained by adding the score from each of the above sections. The individual receives 1 point for each correct answer. The total score can range from 0 to 30, with a higher score indicating better function. A positive change score indicates improvement.
Time Frame	Baseline to Month 1 and 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.
The Safety population was made up of all the randomized patients who had taken at least one dose of the study medication.

Reporting Groups

	Description

Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Measured Values

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine Patch (9.5 mg/Day)	Rivastigmine Capsules (6 mg to 12 mg/Day)
Number of Participants Analyzed **[units: participants]**	**43**	**47**	**49**
Change in the Total Mini-Mental State Examination (MMSE) Score From Baseline to Month 1 and Month 3 **[units: Units on a scale]** **Mean (Standard Deviation)**			
Month 1	**0.12 (2.60)**	**0.59 (2.58)**	**1.00 (2.63)**
Month 3	**-0.59 (2.85)**	**0.12 (2.85)**	**-0.40 (2.42)**

No statistical analysis provided for Change in the Total Mini-Mental State Examination (MMSE) Score From Baseline to Month 1 and Month 3

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description

Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Serious Adverse Events

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine Patch (9.5 mg/Day)	Rivastigmine Capsules (6 mg to 12 mg/Day)
Total, serious adverse events			
# participants affected / at risk	**2/43 (4.65%)**	**3/47 (6.38%)**	**1/49 (2.04%)**
Infections and infestations			
Urinary tract infection †1			
# participants affected / at risk	**1/43 (2.33%)**	**0/47 (0.00%)**	**0/49 (0.00%)**
Injury, poisoning and procedural complications			
Femur fracture †1			
# participants affected / at risk	**0/43 (0.00%)**	**0/47 (0.00%)**	**1/49 (2.04%)**
Nervous system disorders			
Cerebellar haematoma †1			
# participants affected / at risk	**1/43 (2.33%)**	**0/47 (0.00%)**	**0/49 (0.00%)**
Cerebrovascular accident †1			
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**	**0/49 (0.00%)**
Transient ischaemic attack †1			
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**	**0/49 (0.00%)**
Vascular disorders			
Hypertensive crisis †1			

# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**	**0/49 (0.00%)**

† 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
Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	Rivastigmine administered transdermally via patches at increasing doses (1 patch/day of 4.6 mg for the first month, changing to 1 patch/day of 9.5 mg for the remaining two months).
Rivastigmine Patch (9.5 mg/Day)	Rivastigmine administered transdermally via patches at a constant dose (9.5 mg/day for the 3 months of treatment).
Rivastigmine Capsules (6 mg to 12 mg/Day)	Rivastigmine administered orally, following the same regime as prior to randomization (doses between 6 mg and 12 mg/day), which remained unchanged throughout the 3 months of treatment.

Other Adverse Events

	Rivastigmine Patch (4.6 mg/Day Switch to 9.5 mg/Day)	**Rivastigmine Patch (9.5 mg/Day)**	**Rivastigmine Capsules (6 mg to 12 mg/Day)**
Total, other (not including serious) adverse events			
# participants affected / at risk	**8/43 (18.60%)**	**7/47 (14.89%)**	**8/49 (16.33%)**
General disorders			

Application site erythema †1			
# participants affected / at risk	**3/43 (6.98%)**	**5/47 (10.64%)**	**0/49 (0.00%)**
Application site pruritus †1			
# participants affected / at risk	**0/43 (0.00%)**	**3/47 (6.38%)**	**0/49 (0.00%)**
Infections and infestations			
Urinary tract infection †1			
# participants affected / at risk	**2/43 (4.65%)**	**0/47 (0.00%)**	**6/49 (12.24%)**
Psychiatric disorders			
Agitation †1			
# participants affected / at risk	**3/43 (6.98%)**	**0/47 (0.00%)**	**2/49 (4.08%)**

† 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
ClinicalTrials.gov Identifier:	NCT00549601 History of Changes
Other Study ID Numbers:	**CENA713DES07**
Study First Received:	October 24, 2007
Results First Received:	January 5, 2011
Last Updated:	February 24, 2011
Health Authority:	Spain: Agencia Española del Medicamento