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Trial record **1 of 1** for: CENA713DDE15

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Clinical Effectiveness of 10 cm^2 Rivastigmine Patch in Patients With Alzheimer's Disease (ADEPT)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00561392

First received: November 19, 2007
Last updated: April 10, 2012
Last verified: April 2012
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: Non-Randomized; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Alzheimer's Disease
Intervention:	Drug: Rivastigmine 5 and 10 cm^2 patch

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 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Participant Flow: Overall Study

	Rivastigmine 5 and 10 cm^2 Patch
STARTED	**208**
COMPLETED	**155**
NOT COMPLETED	**53**
Adverse Event	**38**
Lack of Efficacy	**2**
Protocol Violation	**1**
Withdrawal by Subject	**8**
Administrative problems	**4**

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 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Baseline Measures

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants [units: participants]	**208**
Age [units: years] Mean (Standard Deviation)	**74 (7.7)**
Gender [units: participants]	
Female	**110**
Male	**98**
Region of Enrollment [units: participants]	

Germany	**208**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Who Completed the Study [Time Frame: Baseline to Week 24]

Measure Type	Primary
Measure Title	Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Who Completed the Study
Measure Description	Dosages of study medication prescribed to and taken by the patient was assessed in a "Drug Administration Record" with start date, end date, dosage and reason for dose adjustment (if applicable). Data was amended by counting the returned medication at the study visits and information by the caregiver.
Time Frame	Baseline to 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.
The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed [units: participants]	**182**
Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Who Completed the Study [units: Percentage of participants] Number (95% Confidence Interval)	**74.2 (67.8 to 80.5)**

No statistical analysis provided for Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Who Completed the Study

2. Primary: Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Regardless Whether They Completed the Study [Time Frame: Baseline to Week 24]

Measure Type	Primary
Measure Title	Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Regardless Whether They Completed the Study
Measure Description	Dosages of study medication prescribed to and taken by the patient was assessed in a "Drug Administration Record" with start date, end date, dosage and reason for dose adjustment (if applicable). Data was amended by counting the returned medication at the study visits and information by the caregiver.
Time Frame	Baseline to 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.

The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed [units: participants]	**182**
Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Regardless Whether They Completed the Study [units: Percentage of participants] Number (95% Confidence Interval)	**80.8 (75.0 to 86.5)**

No statistical analysis provided for Percentage of Participants Treated by Rivastigmine 10 cm^2 Patch for at Least 8 Weeks Regardless Whether They Completed the Study

3. Primary: Percentage of Participants Who Were Compliant to the 10 cm^2 Patch [Time Frame: Baseline to Week 24]

Measure Type	Primary
Measure Title	Percentage of Participants Who Were Compliant to the 10 cm^2 Patch
Measure Description	Dosages of study medication prescribed to and taken by the patient was assessed in a "Drug Administration Record" with start date, end date, dosage and reason for dose adjustment (if applicable). Data was amended by counting the returned medication at the study visits and information by the caregiver.

Time Frame	Baseline to 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.
The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed [units: participants]	**182**
Percentage of Participants Who Were Compliant to the 10 cm^2 Patch [units: Percentage of participants] Mean (Standard Deviation)	**95.0 (28.3)**

No statistical analysis provided for Percentage of Participants Who Were Compliant to the 10 cm^2 Patch

4. Secondary: Mean Change From Baseline in the Mini-Mental State Examination (MMSE) Score at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Mini-Mental State Examination (MMSE) Score at Week 24
Measure Description	The MMSE is a brief, practical screening test for cognitive dysfunction. The test consists of five sections (orientation, registration, attention-calculation, recall, and language); 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 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.
The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed **[units: participants]**	**182**
Mean Change From Baseline in the Mini-Mental State Examination (MMSE) Score at Week 24 **[units: Units on a scale]** **Mean (Standard Deviation)**	**1.3 (3.8)**

No statistical analysis provided for Mean Change From Baseline in the Mini-Mental State Examination (MMSE) Score at Week 24

5. Secondary: Mean Change From Baseline in the Trail-making Test Part A Score at Week 24 [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Trail-making Test Part A Score at Week 24
Measure Description	The Trail-making test is a neuropsychological test of visual attention and task switching. The task requires a subject to 'connect-the-dots' of 25 consecutive numbers (1,2,3, etc.) on a sheet of paper or computer screen. The goal of the subject is to finish the test as quickly as possible, and the time taken to complete the test is used as the primary performance metric (in seconds). The maximum time allowed is 300 seconds. A negative change score indicates improvement.
Time Frame	Baseline to 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.
The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch

Number of Participants Analyzed [units: participants]	**182**
Mean Change From Baseline in the Trail-making Test Part A Score at Week 24 [units: Seconds] Mean (Standard Deviation)	**-8.9 (109.45)**

No statistical analysis provided for Mean Change From Baseline in the Trail-making Test Part A Score at Week 24

6. Secondary: Mean Change From Baseline in the Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) Score at Week 24 [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) Score at Week 24
Measure Description	The ADCS-ADL scale is composed of 23 items developed to assess a patient's performance of both basic and instrumental activities of daily living such as those necessary for personal care, communicating and interacting with other people, maintaining a household, conducting hobbies and interests, as well as making judgments and decisions. Responses for each item will be obtained from the caregiver through an interview. The range for the total ADCS-ADL score is 0 to 78; a higher score indicates a more self-sufficient individual. A positive change score indicates improvement.
Time Frame	Baseline to 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.
The Intent-to-Treat (ITT) population was defined as all patients who were administered at least one dose of study medication and were assessed for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed **[units: participants]**	**182**
Mean Change From Baseline in the Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) Score at Week 24 **[units: Units on a scale]** **Mean (Standard Deviation)**	**1.3 (12.02)**

No statistical analysis provided for Mean Change From Baseline in the Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) Score at Week 24

7. Secondary: Change From Baseline in the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Physician [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Physician
Measure Description	The ADCS-CGIC is an assessment tool to make a judgment of change in a patient's condition. Change is derived from comparing an assessment performed at baseline versus an assessment at the end of the study. Change is categorized into 1 of 7 categories: No change; minimal, moderate, or marked improvement; or minimal, moderate, or marked decline. Results are reported as number of patients in the indicated change category.

Time Frame	Baseline to 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.
The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed [units: participants]	**182**
Change From Baseline in the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Physician [units: Participants]	
No change	**47**
Minimal improvement	**25**
Moderate improvement	**23**
Marked improvement	**15**
Minimal decline	**37**

Moderate decline	**12**
Marked decline	**5**

No statistical analysis provided for Change From Baseline in the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Physician

8. Secondary: Mean Change From Baseline in the Alzheimer's Disease Cooperative Study- Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Caregiver [Time Frame: Baseline t0 Week 24]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Alzheimer's Disease Cooperative Study- Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Caregiver
Measure Description	The ADCS-CGIC is an assessment tool to make a judgment of change in a patient's condition. Change is derived from comparing an assessment performed at baseline versus an assessment at the end of the study. Change is categorized into 1 of 7 categories: No change; minimal, moderate, or marked improvement; or minimal, moderate, or marked decline.
Time Frame	Baseline t0 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.
The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once

	daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed [units: participants]	**182**
Mean Change From Baseline in the Alzheimer's Disease Cooperative Study- Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Caregiver [units: Participants]	
No change	**21**
Minimal improvement	**23**
Moderate improvement	**16**
Marked improvement	**15**
Minimal decline	**56**
Moderate decline	**20**
Marked decline	**14**

No statistical analysis provided for Mean Change From Baseline in the Alzheimer's Disease Cooperative Study- Clinical Global Impression of Change (ADCS-CGIC) at Week 24 Assessed by the Caregiver

9. Secondary: Mean Change From Baseline in the Mini-Zarit Inventory Score of Caregiver Burden at Week 24 [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Mini-Zarit Inventory Score of Caregiver Burden at Week 24

Measure Description	The Mini-Zarit Inventory assesses the burden of a caregiver in caring for a patient. The inventory is composed of 5 questions which are rated according to the following answers: 0 = never, ½ = sometimes, 1 = often. The ratings on the 5 questions are added together resulting in a total score of 0 to 7 with a higher score indicating greater caregiver burden. A negative change score indicates reduced burden.
Time Frame	Baseline to 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.
The Intent-to-Treat (ITT) population was defined as all randomized patients who were administered at least one dose of study medication and were assessed at baseline and post-baseline for efficacy at least 1 time.

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Measured Values

	Rivastigmine 5 and 10 cm^2 Patch
Number of Participants Analyzed **[units: participants]**	**182**
Mean Change From Baseline in the Mini-Zarit Inventory Score of Caregiver Burden at Week 24 **[units: Units on a scale]** **Mean (Standard Deviation)**	**0.4 (1.58)**

No statistical analysis provided for Mean Change From Baseline in the Mini-Zarit Inventory Score of Caregiver Burden at Week 24

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Rivastigmine 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Serious Adverse Events

	Rivastigmine 5 and 10 cm^2 Patch
Total, serious adverse events	
# participants affected / at risk	**18/208 (8.65%)**
Cardiac disorders	
Bradycardia † 1	
# participants affected / at risk	**1/208 (0.48%)**
General disorders	
Death † 1	
# participants affected / at risk	**1/208 (0.48%)**
Fatigue † 1	
# participants affected / at risk	**1/208 (0.48%)**
Malaise † 1	

# participants affected / at risk	1/208 (0.48%)
Infections and infestations	
Bronchitis † 1	
# participants affected / at risk	1/208 (0.48%)
Injury, poisoning and procedural complications	
Fall † 1	
# participants affected / at risk	1/208 (0.48%)
Femoral neck fracture † 1	
# participants affected / at risk	1/208 (0.48%)
Investigations	
Blood glucose abnormal † 1	
# participants affected / at risk	1/208 (0.48%)
Metabolism and nutrition disorders	
Dehydration † 1	
# participants affected / at risk	1/208 (0.48%)
Musculoskeletal and connective tissue disorders	
Back pain † 1	
# participants affected / at risk	1/208 (0.48%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Brain neoplasm † 1	
# participants affected / at risk	1/208 (0.48%)
Nervous system disorders	
Cerebrovascular accident † 1	
# participants affected / at risk	1/208 (0.48%)

Cognitive disorder † 1	
# participants affected / at risk	**1/208 (0.48%)**
Dementia Alzheimer's type † 1	
# participants affected / at risk	**3/208 (1.44%)**
Dysstasis † 1	
# participants affected / at risk	**1/208 (0.48%)**
Grand mal convulsion † 1	
# participants affected / at risk	**1/208 (0.48%)**
Syncope † 1	
# participants affected / at risk	**1/208 (0.48%)**
Psychiatric disorders	
Aggression † 1	
# participants affected / at risk	**1/208 (0.48%)**
Confusional state † 1	
# participants affected / at risk	**2/208 (0.96%)**
Disorientation † 1	
# participants affected / at risk	**1/208 (0.48%)**
Psychotic disorder † 1	
# participants affected / at risk	**1/208 (0.48%)**
Renal and urinary disorders	
Incontinence † 1	
# participants affected / at risk	**1/208 (0.48%)**
Vascular disorders	
Circulatory collapse † 1	
# participants affected / at risk	**1/208 (0.48%)**

Deep vein thrombosis † 1	
# participants affected / at risk	**1/208 (0.48%)**
Hypertensive crisis † 1	
# participants affected / at risk	**1/208 (0.48%)**

† Events were collected by systematic assessment
1 Term from vocabulary, 12.1

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 5 and 10 cm^2 Patch	For the 1st 4 weeks of this 24 week study, patients were administered rivastigmine transdermally once daily via a 5 cm^2 patch. After the Week 4 assessment, patients were administered rivastigmine transdermally once daily via a 10 cm^2 patch, with adjustments as necessary for safety and tolerability.

Other Adverse Events

	Rivastigmine 5 and 10 cm^2 Patch
Total, other (not including serious) adverse events	
# participants affected / at risk	**49/208 (23.56%)**

Gastrointestinal disorders	
Nausea † 1	
# participants affected / at risk	**21/208 (10.10%)**
Vomiting † 1	
# participants affected / at risk	**15/208 (7.21%)**
Skin and subcutaneous tissue disorders	
Erythema † 1	
# participants affected / at risk	**18/208 (8.65%)**
Pruritus † 1	
# participants affected / at risk	**17/208 (8.17%)**

† Events were collected by systematic assessment
1 Term from vocabulary, 12.1

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 by Novartis

Publications automatically indexed to this study:

Articus K, Baier M, Tracik F, Kühn F, Preuss UW, Kurz A. A 24-week, multicentre, open evaluation of the clinical effectiveness of the rivastigmine patch in patients with probable Alzheimer's disease. Int J Clin Pract. 2011 Jul;65(7):790-6. doi: 10.1111/j.1742-1241.2011.02713.x. Epub 2011 Jun 6.

Responsible Party:	External Affairs, Novartis
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Results First Received:	December 15, 2010
Last Updated:	April 10, 2012
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