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Trial record **1 of 1** for: CENA713DDE18

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Rivastigmine in Multiple Sclerosis Patients With Cognitive Impairment (EXCITING)

This study has been terminated.

(Termination of study due to low enrollment)

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00881205

First received: April 14, 2009
Last updated: March 8, 2012
Last verified: March 2012
History of Changes

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Results First Received: January 20, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Multiple Sclerosis Cognitive Impairment
Interventions:	Drug: Rivastigmine transdermal patch 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
Rivastigmine	5 and 10 cm² patch sizes (4,6mg/24h or 9,5mg/24h) of rivastigmine,
Placebo	Matching the size, shape and color of rivastigmine patches.

Participant Flow: Overall Study

	Rivastigmine	Placebo
STARTED	**45**	**41**
COMPLETED	**34**	**34**
NOT COMPLETED	**11**	**7**
Adverse Event	**8**	**3**
Withdrawal by Subject	**1**	**2**
Lost to Follow-up	**0**	**1**
Administrative problems	**1**	**1**
Condition no longer requires drug	**1**	**0**

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 cm² patch sizes (4,6mg/24h or 9,5mg/24h) of rivastigmine,
Placebo	Matching the size, shape and color of rivastigmine patches.
Total	Total of all reporting groups

Baseline Measures

	Rivastigmine	**Placebo**	**Total**
Number of Participants [units: participants]	**43**	**38**	**81**
Age [units: years] Mean (Standard Deviation)	**44.6 (9.4)**	**44.0 (7.3)**	**44.3 (8.5)**
Gender [units: participants]			
Female	**23**	**20**	**43**
Male	**20**	**18**	**38**

Outcome Measures

1. Primary: Change From Baseline to Week 16 in Total Recall on the Selective Reminding Test (SRT) in the Intent to Treat (ITT) Population [Time Frame: After 16 weeks of treatment]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Change From Baseline to Week 16 in Total Recall on the Selective Reminding Test (SRT) in the Intent to Treat (ITT) Population
Measure Description	The Selective Reminding Test(SRT) is a test to assess verbal learning and memory. During the administration of the SRT only the examiner and the patient should be in the testing room. A list of twelve words is read aloud by the examiner at a rate of one word per two seconds. The patient is asked to recall all twelve words. Only the words that are missed on the preceding trial are given in the consecutive trial. The total score represents a sum score of 6 trials, therefore the range is from 0-72. The lower the value the worse the outcome.
Time Frame	After 16 weeks of treatment
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.
Due to low enrollment numbers study did not achieve the anticipated 80% power.

Reporting Groups

	Description
Rivastigmine	5 and 10 cm² patch sizes (4,6mg/24h or 9,5mg/24h) of rivastigmine,
Placebo	Matching the size, shape and color of rivastigmine patches.

Measured Values

	Rivastigmine	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change From Baseline to Week 16 in Total Recall on the Selective Reminding Test (SRT) in the Intent to Treat (ITT) Population		

[units: units on a scale] **Mean (Standard Deviation)**		

No statistical analysis provided for Change From Baseline to Week 16 in Total Recall on the Selective Reminding Test (SRT) in the Intent to Treat (ITT) Population

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The safety population will consist of all patients that received at least one dose of study drug and had at least one post-baseline safety assessment. Patients will be analyzed according to treatment received.

Reporting Groups

	Description
Total Patients	Total Patients
Rivastigmine	Rivastigmine patch arm with the application of one 5 cm² patch, followed by an increase to the target dose of 10 cm² patch size
Placebo	Placebo patch arm with the application of one 5 cm² patch, followed by an increase to the target dose of 10 cm² patch size

Serious Adverse Events

	Total Patients	Rivastigmine	Placebo
Total, serious adverse events			
# participants affected / at risk	**6/86 (6.98%)**	**2/45 (4.44%)**	**4/41 (9.76%)**
Gastrointestinal disorders			
NAUSEA †1			
# participants affected / at risk	**1/86 (1.16%)**	**0/45 (0.00%)**	**1/41 (2.44%)**
General disorders			

OEDEMA PERIPHERAL †1			
# participants affected / at risk	**1/86 (1.16%)**	**0/45 (0.00%)**	**1/41 (2.44%)**
PYREXIA †1			
# participants affected / at risk	**1/86 (1.16%)**	**0/45 (0.00%)**	**1/41 (2.44%)**
Infections and infestations			
CELLULITIS †1			
# participants affected / at risk	**1/86 (1.16%)**	**1/45 (2.22%)**	**0/41 (0.00%)**
PYELONEPHRITIS †1			
# participants affected / at risk	**1/86 (1.16%)**	**1/45 (2.22%)**	**0/41 (0.00%)**
SEPSIS †1			
# participants affected / at risk	**1/86 (1.16%)**	**1/45 (2.22%)**	**0/41 (0.00%)**
Nervous system disorders			
DIZZINESS †1			
# participants affected / at risk	**1/86 (1.16%)**	**0/45 (0.00%)**	**1/41 (2.44%)**
OPTIC NEURITIS †1			
# participants affected / at risk	**1/86 (1.16%)**	**0/45 (0.00%)**	**1/41 (2.44%)**
Psychiatric disorders			
DEPRESSION †1			
# participants affected / at risk	**1/86 (1.16%)**	**0/45 (0.00%)**	**1/41 (2.44%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	The safety population will consist of all patients that received at least one dose of study drug and had at least one post-baseline

	safety assessment. Patients will be analyzed according to treatment received.

Frequency Threshold

Threshold above which other adverse events are reported	3%

Reporting Groups

	Description
Total Patients	Total Patients
Rivastigmine	Rivastigmine patch arm with the application of one 5 cm² patch, followed by an increase to the target dose of 10 cm² patch size
Placebo	Placebo patch arm with the application of one 5 cm² patch, followed by an increase to the target dose of 10 cm² patch size

Other Adverse Events

	Total Patients	Rivastigmine	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**48/86 (55.81%)**	**25/45 (55.56%)**	**23/41 (56.10%)**
Ear and labyrinth disorders			
VERTIGO †1			
# participants affected / at risk	**3/86 (3.49%)**	**2/45 (4.44%)**	**1/41 (2.44%)**
Gastrointestinal disorders			
DIARRHOEA †1			
# participants affected / at risk	**3/86 (3.49%)**	**1/45 (2.22%)**	**2/41 (4.88%)**
NAUSEA †1			
# participants affected / at risk	**6/86 (6.98%)**	**2/45 (4.44%)**	**4/41 (9.76%)**
VOMITING †1			
# participants affected / at risk	**3/86 (3.49%)**	**2/45 (4.44%)**	**1/41 (2.44%)**
General disorders			
CHILLS †1			
# participants affected / at risk	**2/86 (2.33%)**	**2/45 (4.44%)**	**0/41 (0.00%)**

INFLUENZA LIKE ILLNESS †1			
# participants affected / at risk	**3/86 (3.49%)**	**1/45 (2.22%)**	**2/41 (4.88%)**
Infections and infestations			
NASOPHARYNGITIS †1			
# participants affected / at risk	**7/86 (8.14%)**	**6/45 (13.33%)**	**1/41 (2.44%)**
RESPIRATORY TRACT INFECTION †1			
# participants affected / at risk	**2/86 (2.33%)**	**0/45 (0.00%)**	**2/41 (4.88%)**
Musculoskeletal and connective tissue disorders			
MUSCLE SPASMS †1			
# participants affected / at risk	**2/86 (2.33%)**	**2/45 (4.44%)**	**0/41 (0.00%)**
Nervous system disorders			
DIZZINESS †1			
# participants affected / at risk	**2/86 (2.33%)**	**0/45 (0.00%)**	**2/41 (4.88%)**
MULTIPLE SCLEROSIS RELAPSE †1			
# participants affected / at risk	**10/86 (11.63%)**	**4/45 (8.89%)**	**6/41 (14.63%)**
Psychiatric disorders			
DEPRESSION †1			
# participants affected / at risk	**5/86 (5.81%)**	**1/45 (2.22%)**	**4/41 (9.76%)**
Respiratory, thoracic and mediastinal disorders			
COUGH †1			
# participants affected / at risk	**3/86 (3.49%)**	**1/45 (2.22%)**	**2/41 (4.88%)**
Skin and subcutaneous tissue disorders			
ERYTHEMA †1			
# participants affected / at risk	**13/86 (15.12%)**	**7/45 (15.56%)**	**6/41 (14.63%)**
PRURITUS †1			
# participants affected / at risk	**3/86 (3.49%)**	**2/45 (4.44%)**	**1/41 (2.44%)**
RASH †1			

# participants affected / at risk	**7/86 (8.14%)**	**5/45 (11.11%)**	**2/41 (4.88%)**
SKIN IRRITATION †1			
# participants affected / at risk	**2/86 (2.33%)**	**0/45 (0.00%)**	**2/41 (4.88%)**
SKIN REACTION †1			
# participants affected / at risk	**3/86 (3.49%)**	**1/45 (2.22%)**	**2/41 (4.88%)**
Vascular disorders			
HYPERTENSION †1			
# participants affected / at risk	**3/86 (3.49%)**	**2/45 (4.44%)**	**1/41 (2.44%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

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
This study was terminated early due to low recruitment numbers. This study did not have the anticipated 80% power.

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 or disclosure of trial results in their entirety.

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00881205 History of Changes
Other Study ID Numbers:	**CENA713DDE18**
Study First Received:	April 14, 2009
Results First Received:	January 20, 2012
Last Updated:	March 8, 2012
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices