A Study to Test the Performance of the CogState Computerized Neuropsychological Battery in Patients With Alzheimer's Disease (0000-086)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00777608

First received: October 21, 2008
Last updated: August 11, 2015
Last verified: August 2015
History of Changes

Purpose

This study will evaluate the performance of the CogState computerized neuropsychological battery, Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-cog) and Alzheimer's Disease Cooperative Study - Activities of Daily Living (ADCS-ADL) in participants with mild-to-moderate Alzheimer's disease (AD).

Condition	Intervention	Phase
Alzheimer's Disease	Drug: Comparator: Placebo 5mg (run in) Drug: Donepezil 5 - 10 mg Drug: Comparator: Placebo 5-10 mg Drug: Donepezil 10 mg	Phase 1

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial, With Placebo Run-In, and an Open-Label Treatment Period, to Evaluate the Performance of the CogState Computerized Neuropsychological Battery and the ADAS-Cog in Generally Cholinesterase-naive AD Patients

Resource links provided by NLM:

Genetics Home Reference related topics: Alzheimer disease

MedlinePlus related topics: Alzheimer's Disease

Drug Information available for: Donepezil hydrochloride Donepezil

Genetic and Rare Diseases Information Center resources: Familial Alzheimer Disease

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Change in Mean Computer-based Cognitive Assessment (CogState) Composite Score at Week 4 [Time Frame: Baseline and 4 weeks] [Designated as safety issue: No]

  CogState is a simple, brief computerized neuropsychological battery to evaluate cognitive impairments characterizing mild-to-moderate Alzheimer's Disease (AD). The composite CogState assesses attention and memory functions - including Verbal episodic memory, Visual Episodic Memory, Psychomotor function, Visual attention and working memory. CogState scores are measured on a linear scale (with no maximum score) and a reduction in scores compared to baseline indicates an improvement in cognitive functions. Reported here is the change in the CogState Composite Score at Week 4 compared to baseline.

Secondary Outcome Measures:

- Evaluate the Efficacy of Donepezil by Determining the Change in Mean CogState Composite Score at Week 2, Week 8 and Week 12 [Time Frame: Baseline and 2 weeks, 8 weeks and 12 weeks] [Designated as safety issue: No]

  CogState is a simple, brief computerized neuropsychological battery to evaluate cognitive impairments characterizing mild-to-moderate Alzheimer's Disease (AD). The composite CogState assesses attention and memory functions - including Verbal episodic memory, Visual Episodic Memory, Psychomotor function, Visual attention and working memory. CogState scores are measured on a linear scale (no maximum score) and a reduction in scores compared to baseline indicates an improvement in cognitive functions. Reported here is the change from baseline in the CogState Composite Score at Weeks 4, 8 and 12.

- Evaluate the Efficacy of Donepezil by Determining the Change in Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) Score at Week 4, Week 8 and Week 12 [Time Frame: Baseline and 4 weeks, 8 weeks and 12 weeks.] [Designated as safety issue: No]

  The ADAS-Cog is a psychometric instrument that evaluates memory, attention, reasoning, language, orientation and praxis using an 11-point AD Assessment Scale. It has a minimum score of 0 and a maximum severity score of 70, and a higher score indicates more impairment. A reduction in scores compared to baseline indicates an improvement in cognitive functions. Reported here is the change in the ADAS-Cog score at Weeks 4, 8 and 12 compared to baseline.

Enrollment:	106
Study Start Date:	December 2008
Study Completion Date:	April 2010
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Donepezil 5-10 mg There will be a 14 day period when all participants will receive placebo, followed by 5 mg donepezil, once daily for 14 days then titrated to 10 mg donepezil once daily for 70 days. Participants may then receive open-label donepezil for an additional 24 weeks.	Drug: Comparator: Placebo 5mg (run in) Matching placebo to donepezil - 5 mg capsules orally for 14 day run in prior to randomization. Drug: Donepezil 5 - 10 mg Donepezil 1 capsule (5 mg) orally, once daily for 14 days. Donepezil 2 capsules (total 10 mg) once daily for 70 days (days 15-84). Drug: Donepezil 10 mg Donepezil 2 capsules (total 10 mg) orally, once daily for 24 weeks, from day 85 (optional).
Placebo Comparator: Placebo There will be a 14 day period when all participants will receive placebo. Participants will take placebo capsules orally, once daily for 84 days. Participants may then receive open-label donepezil for an additional 24 weeks.	Drug: Comparator: Placebo 5mg (run in) Matching placebo to donepezil - 5 mg capsules orally for 14 day run in

	prior to randomization. Drug: Comparator: Placebo 5-10 mg Matching placebo to donepezil, 1 capsule (5 mg) orally, once daily for 14 days. Matching placebo to donepezil 2 capsules (total 10 mg) once daily for 70 days (days 15-84). Drug: Donepezil 10 mg Donepezil 2 capsules (total 10 mg) orally, once daily for 24 weeks, from day 85 (optional).

Eligibility

Ages Eligible for Study: 55 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Participant is ambulatory, male or female and 55 years of age or older
- Participant has reliable informant/caregiver who can communicate effectively with the study site and personnel

Exclusion Criteria:

- Participant has a history within the last 6 months or current evidence of a psychotic disorder or an active major depressive disorder or participant has any history of schizophrenia
- Participant has a history of multiple and/or serious allergies to drugs or food or a history of an allergic reaction to more than 3 drug classes

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00777608

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00777608 History of Changes
Other Study ID Numbers: 0000-086 2008_573
Study First Received: October 21, 2008
Results First Received: January 27, 2011
Last Updated: August 11, 2015
Health Authority: Hungary: National Institute of Pharmacy

Additional relevant MeSH terms:

Alzheimer Disease
Brain Diseases
Central Nervous System Diseases
Delirium, Dementia, Amnestic, Cognitive Disorders
Dementia
Mental Disorders
Nervous System Diseases
Neurodegenerative Diseases
Tauopathies
Donepezil

Central Nervous System Agents
Cholinergic Agents
Cholinesterase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Neurotransmitter Agents
Nootropic Agents
Pharmacologic Actions
Physiological Effects of Drugs
Therapeutic Uses

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ClinicalTrials.gov Identifier:
NCT00777608

First received: October 21, 2008
Last updated: August 11, 2015
Last verified: August 2015
History of Changes

Results First Received: January 27, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Alzheimer's Disease
Interventions:	Drug: Comparator: Placebo 5mg (run in) Drug: Donepezil 5 - 10 mg Drug: Comparator: Placebo 5-10 mg Drug: Donepezil 10 mg

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
Donepezil 5-10 mg	Participants were randomized to donepezil for 84 days
Placebo	Participants were randomized to placebo for 84 days

Participant Flow: Overall Study

	Donepezil 5-10 mg	Placebo
STARTED	**53**	**53**
COMPLETED	**49**	**47**
NOT COMPLETED	**4**	**6**
Lost to Follow-up	**1**	**1**
Withdrawal by Subject	**1**	**3**
Protocol Violation	**1**	**0**
Investigator Decision	**1**	**2**

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
Donepezil 5-10 mg	Participants were randomized to donepezil for 84 days
Placebo	Participants were randomized to placebo for 84 days
Total	Total of all reporting groups

Baseline Measures

	Donepezil 5-10 mg	Placebo	Total
Number of Participants [units: participants]	**53**	**53**	**106**
Age, Customized [1] [units: Participants]	**53**	**53**	**106**
Gender			

[units: participants]			
Female	23	22	45
Male	30	31	61

[1] Age >= 55 years

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Mean Computer-based Cognitive Assessment (CogState) Composite Score at Week 4 [Time Frame: Baseline and 4 weeks]

Measure Type	Primary
Measure Title	Change in Mean Computer-based Cognitive Assessment (CogState) Composite Score at Week 4
Measure Description	CogState is a simple, brief computerized neuropsychological battery to evaluate cognitive impairments characterizing mild-to-moderate Alzheimer's Disease (AD). The composite CogState assesses attention and memory functions - including Verbal episodic memory, Visual Episodic Memory, Psychomotor function, Visual attention and working memory. CogState scores are measured on a linear scale (with no maximum score) and a reduction in scores compared to baseline indicates an improvement in cognitive functions. Reported here is the change in the CogState Composite Score at Week 4 compared to baseline.
Time Frame	Baseline and 4 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.
The analysis for the primary and secondary CogState endpoints was done on a per protocol basis (only participants who were compliant and successfully tolerated the forced titration after 2 weeks of treatment were included in the analysis).

Reporting Groups

	Description
Donepezil 5-10 mg	Participants were randomized to donepezil for 84 days
Placebo	Participants were randomized to placebo for 84 days

Measured Values

	Donepezil 5-10 mg	Placebo
Number of Participants Analyzed [units: participants]	**38**	**43**
Change in Mean Computer-based Cognitive Assessment (CogState) Composite Score at Week 4 [units: Score on a scale] Least Squares Mean (Standard Error)	**-0.10 (0.07)**	**-0.07 (0.06)**

Statistical Analysis 1 for Change in Mean Computer-based Cognitive Assessment (CogState) Composite Score at Week 4

Groups [1]	All groups

Method [2]	ANOVA
P Value [3]	0.231
Mean Difference (Final Values) [4]	-0.07
90% Confidence Interval	-0.2 to 0.08

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Evaluate the Efficacy of Donepezil by Determining the Change in Mean CogState Composite Score at Week 2, Week 8 and Week 12 [Time Frame: Baseline and 2 weeks, 8 weeks and 12 weeks]

Measure Type	Secondary
Measure Title	Evaluate the Efficacy of Donepezil by Determining the Change in Mean CogState Composite Score at Week 2, Week 8 and Week 12
Measure Description	CogState is a simple, brief computerized neuropsychological battery to evaluate cognitive impairments characterizing mild-to-moderate Alzheimer's Disease (AD). The composite CogState assesses attention and memory functions - including Verbal episodic memory, Visual Episodic Memory, Psychomotor function, Visual attention and working memory. CogState scores are measured on a linear scale (no maximum score) and a reduction in scores compared to baseline indicates an improvement in cognitive functions. Reported here is the change from baseline in the CogState Composite Score at Weeks 4, 8 and 12.
Time Frame	Baseline and 2 weeks, 8 weeks and 12 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.
The analysis for the primary and secondary CogState endpoints was done on a per protocol basis (only participants who were compliant and successfully tolerated the forced titration after 2 weeks of treatment were included in the analysis).

Reporting Groups

	Description
Donepezil 5-10 mg	Participants were randomized to donepezil for 84 days
Placebo	Participants were randomized to placebo for 84 days

Measured Values

	Donepezil 5-10 mg	Placebo
Number of Participants Analyzed [units: participants]	**38**	**43**
Evaluate the Efficacy of Donepezil by Determining the Change in Mean CogState Composite Score at Week 2, Week 8 and Week 12 [units: Score on a scale] Least Squares Mean (Standard Error)		
Week 2 (N=38, N=43)	**-0.2 (0.07)**	**-0.006 (0.06)**
Week 8 (N=38, N=40)	**-0.1 (0.07)**	**-0.02 (0.07)**
Week 12 (N=38, N=41)	**-0.2 (0.07)**	**-0.09 (0.07)**

Statistical Analysis 1 for Evaluate the Efficacy of Donepezil by Determining the Change in Mean CogState Composite Score at Week 2, Week 8 and Week 12

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.041
Mean Difference (Final Values) [4]	-0.2
Standard Error of the mean	(0.09)
90% Confidence Interval	-0.3 to -0.008

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Statistical analysis for Week 2

Statistical Analysis 2 for Evaluate the Efficacy of Donepezil by Determining the Change in Mean CogState Composite Score at Week 2, Week 8 and Week 12

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.143
Mean Difference (Final Values) [4]	-0.1
Standard Error of the mean	(0.09)

90% Confidence Interval	-0.3 to 0.06

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Statistical analysis for Week 8

Statistical Analysis 3 for Evaluate the Efficacy of Donepezil by Determining the Change in Mean CogState Composite Score at Week 2, Week 8 and Week 12

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.226
Mean Difference (Final Values) [4]	-0.07
Standard Error of the mean	(0.10)
90% Confidence Interval	-0.2 to 0.09

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Statistical analysis for Week 12

3. Secondary: Evaluate the Efficacy of Donepezil by Determining the Change in Alzheimer’s Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) Score at Week 4, Week 8 and Week 12 [Time Frame: Baseline and 4 weeks, 8 weeks and 12 weeks.]

Measure Type	Secondary
Measure Title	Evaluate the Efficacy of Donepezil by Determining the Change in Alzheimer’s Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) Score at Week 4, Week 8 and Week 12
Measure Description	The ADAS-Cog is a psychometric instrument that evaluates memory, attention, reasoning, language, orientation and praxis using an 11-point AD Assessment Scale. It has a minimum score of 0 and a maximum severity score of 70, and a higher score indicates more impairment. A reduction in scores compared to baseline indicates an improvement in cognitive functions. Reported here is the change in the ADAS-Cog score at Weeks 4, 8 and 12 compared to baseline.

Time Frame	Baseline and 4 weeks, 8 weeks and 12 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.
The analysis for the primary and secondary CogState endpoints was done on a per protocol basis (only participants who were compliant and successfully tolerated the forced titration after 2 weeks of treatment were included in the analysis).

Reporting Groups

	Description
Donepezil 5-10 mg	Participants were randomized to donepezil for 84 days
Placebo	Participants were randomized to placebo for 84 days

Measured Values

	Donepezil 5-10 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**38**	**43**
Evaluate the Efficacy of Donepezil by Determining the Change in Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) Score at Week 4, Week 8 and Week 12 [units: Score on a scale] Least Squares Mean (Standard Error)		
Week 4 (N=38, N=43)	**0.2 (0.8)**	**-0.3 (0.7)**
Week 8 (N=37, N=40)	**0.07 (1.0)**	**-0.7 (1.0)**
Week 12 (N=38, N=40)	**-1.4 (1.0)**	**-1.0 (1.0)**

Statistical Analysis 1 for Evaluate the Efficacy of Donepezil by Determining the Change in Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) Score at Week 4, Week 8 and Week 12

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.324
Mean Difference (Final Values) [4]	0.5
Standard Error of the mean	(1.0)
90% Confidence Interval	-1.2 to 2.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Statistical analysis for Week 4

Statistical Analysis 2 for Evaluate the Efficacy of Donepezil by Determining the Change in Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) Score at Week 4, Week 8 and Week 12

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.285
Mean Difference (Final Values) [4]	0.8
Standard Error of the mean	(1.4)
90% Confidence Interval	-1.5 to 3.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Evaluate the Efficacy of Donepezil by Determining the Change in Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) Score at Week 4, Week 8 and Week 12

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.401
Mean Difference (Final Values) [4]	-0.3
Standard Error of the mean	(1.3)
90% Confidence Interval	-2.6 to 1.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical

	significance:
	No text entered.
[4]	Other relevant estimation information:
	Statistical analysis for Week 12

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Donezepil 5-10 mg	Participants were randomized to donepezil for 84 days
Placebo	Participants were randomized to placebo for 84 days

Serious Adverse Events

	Donezepil 5-10 mg	Placebo
Total, serious adverse events		
# participants affected / at risk	**3/53 (5.66%)**	**0/53 (0.00%)**
Gastrointestinal disorders		
Inguinal hernia		
# participants affected / at risk	**1/53 (1.89%)**	**0/53 (0.00%)**
Injury, poisoning and procedural complications		
Head Injury		
# participants affected / at risk	**1/53 (1.89%)**	**0/53 (0.00%)**
Subdural haematoma		
# participants affected / at risk	**1/53 (1.89%)**	**0/53 (0.00%)**
Nervous system disorders		
Convulsion		
# participants affected / at risk	**1/53 (1.89%)**	**0/53 (0.00%)**
Renal and urinary disorders		
Urinary incontinence		
# participants affected / at risk	**1/53 (1.89%)**	**0/53 (0.00%)**

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
Donezepil 5-10 mg	Participants were randomized to donepezil for 84 days
Placebo	Participants were randomized to placebo for 84 days

Other Adverse Events

	Donezepil 5-10 mg	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**10/53 (18.87%)**	**9/53 (16.98%)**
Gastrointestinal disorders		
Nausea [*1]		
# participants affected / at risk	**7/53 (13.21%)**	**5/53 (9.43%)**
Nervous system disorders		
Dizziness [*1]		
# participants affected / at risk	**3/53 (5.66%)**	**4/53 (7.55%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 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 **NOT** 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.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp and Dohme Corp
e-mail: ClinicalTrialsDisclosure@merck.com

Responsible Party:	Merck Sharp & Dohme Corp.
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Last Updated:	August 11, 2015
Health Authority:	Hungary: National Institute of Pharmacy

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