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Protocol Registration and Results System

ID: 10112 A Clinical Study Evaluating the Effects of Memantine on Brain Atrophy in Patients With Alzheimer's Disease NCT00862940

Protocol Registration and Results Preview

Close

A Clinical Study Evaluating the Effects of Memantine on Brain Atrophy in Patients With Alzheimer's Disease

This study has been completed.

Sponsor:	H. Lundbeck A/S
Collaborators:	
Information provided by (Responsible Party):	H. Lundbeck A/S
ClinicalTrials.gov Identifier:	NCT00862940

Purpose

Pre-clinical studies have demonstrated that memantine can decrease the neuronal toxicity associated with excessive glutamate release and calcium overload in neurons. Previous studies have shown that memantine helps to treat the symptoms of Alzheimer's Disease (AD). In AD, the rate of brain tissue loss, or atrophy, is faster than in normal aging and this seems to go hand in hand with some of the symptoms of the disease. This suggests that memantine treatment in AD could provide both symptomatic improvement and neuro-protective effects. The purpose of this study was to show whether memantine, in addition to providing symptomatic benefits, can slow the rate of brain atrophy as assessed using magnetic resonance imaging (MRI) technology.

Condition	Intervention	Phase
Alzheimer's Disease	Drug: Memantine Drug: Placebo	Phase 4

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Efficacy Study

Official Title: A 1-year Randomised, Double-blind Placebo-controlled Study to Evaluate the Effects of Memantine on Rate of Brain Atrophy in Patients With Alzheimer's Disease

Further study details as provided by H. Lundbeck A/S:

Primary Outcome Measure:

- Total Brain Atrophy Rate Estimated Using Brain Boundary Shift Integral (BBSI) [Time Frame: Baseline to 1 year] [Designated as safety issue: No]
  Measures direct changes in total brain volume per visit interval (screening to Week 4,

42, or 52 or from Week 4 to Week 42 or 52)

Secondary Outcome Measures:

- Changes in Total Hippocampal Volume (HCV) [Time Frame: Baseline to 1 year] [Designated as safety issue: No]
  Estimated mean changes in total HCV

- Cognitive and Behavioural Outcomes: Controlled Oral Word Association Test (COWAT) Total Score [Time Frame: Baseline to 1 year] [Designated as safety issue: No]
  Adjusted mean change from baseline on cognitive and behavioural scores. COWAT: Verbal fluency test. The patient was asked to, during 1 minute, generate as many words as possible beginning with three pre-specified letters. The total score was calculated as the sum of acceptable words generated, with higher scores indicating lower cognitive impairment

- Cognitive and Behavioural Outcomes: Mini Mental State Examination (MMSE) Total Score [Time Frame: Baseline to 1 year] [Designated as safety issue: No]
  Adjusted mean change from baseline on cognitive and behavioural scores. MMSE: Brief, structured examination of mental status that assesses orientation, memory, attention, naming, comprehension, and praxis. The range is 0 to 30, with a lower score indicating a worse mental state

Enrollment: 277
Study Start Date: September 2005
Study Completion Date: April 2009
Primary Completion Date: February 2009

Arms	Assigned Interventions
Experimental: Memantine	Drug: Memantine 10 mg tablets twice daily Other Names: • Ebixa®
Placebo Comparator: Placebo	Drug: Placebo Tablets twice daily

The primary objective of this study was to evaluate the effects of memantine on the rate of brain atrophy compared to placebo in patients with AD (moderate severity) over a 1-year period. This was a multinational, randomised, double-blind, parallel-group, placebo-controlled, fixed-dose study (20 mg memantine). The study also included secondary imaging, cognitive and behavioural measures.

Eligibility

Ages Eligible for Study: 50 Years and older
Genders Eligible for Study: Both
Inclusion Criteria:

- Outpatients at least 50 years of age with a current diagnosis of probable AD of moderate severity (MMSE score between 12 and 20, inclusive) consistent with NINCDS-ADRDA criteria

and MRI scans

- Patients must have had a knowledgeable and reliable caregiver to accompany them to all clinic visits during the study
- Patients were either on or off existing acetylcholinesterase inhibitor (AChEI) treatment provided that the treatment had been initiated >6 months prior to screening, had stabilised with respect to dose for >3 months, and remained fixed during the entire study. AChEI treatment could not be initiated or modified during the study

Exclusion Criteria:

- The patient had evidence of clinically significant active disease (including recent myocardial infarction and uncompensated congestive heart failure [NYHA II-IV])
- The patient had evidence of any clinically significant neurodegenerative disease or neurological disorder other than AD
- The patient was contraindicated for MRI

Other protocol-defined inclusion and exclusion criteria applied.

Contacts and Locations

Investigators

Study Director:	Email contact via H. Lundbeck A/S	LundbeckClinicalTrials@lundbeck.com

More Information

Results Publications:

Wilkinson D, Fox NC, Barkhof F, Phul R, Lemming O, Scheltens P. Memantine and brain atrophy in Alzheimer's disease: a 1-year randomized controlled trial. J Alzheimers Dis. 2012;29(2):459-69. doi: 10.3233/JAD-2011-111616.

Responsible Party: H. Lundbeck A/S
Study ID Numbers: 10112
2004-002614-10 [EudraCT Number]
Health Authority: France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)
Germany: Federal Institute for Drugs and Medical Devices
Switzerland: Swissmedic
United Kingdom: Medicines and Healthcare Products Regulatory Agency

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Study Results

Participant Flow

Recruitment Details	The patients were recruited from each investigator's outpatient clinic.
Pre-Assignment Details	After a 3-week run-in period during which MRI scans were performed, the patients were randomised to either placebo or memantine and stratified according to AChEI treatment. Memantine-treated patients started with 5 mg/day and were uptitrated by 5 mg/day every week for 4 weeks. The target dose of 20 mg/day was administered from the start of

	Week 4.

Arm/Group Title	Memantine 10 mg Tablets Twice Daily	Placebo Tablets Twice Daily	Total (Not public)
▼ Arm/Group Description	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	
Period Title: **Overall Study**			
Started	133	144	277
Completed	103	114	217
Not Completed	30	30	60
Reason Not Completed			
Adverse Event	15	12	27
Lack of Efficacy	1	3	4
Protocol Violation	2	5	7
Withdrawal by Subject	4	6	10
Non-compliance	4	0	4
Lost to Follow-up	0	1	1
Administrative or other reason(s)	4	3	7
(Not Public)	Not Completed = 30 Total from all reasons = 30	Not Completed = 30 Total from all reasons = 30	

Baseline Characteristics

Arm/Group Title	Memantine 10 mg Tablets Twice Daily	Placebo Tablets Twice Daily	Total
▼ Arm/Group Description	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	
Overall Number of Baseline Participants	133	144	**277**
▼ Baseline Analysis Population Description [Not specified]			
Age, Continuous Mean (Standard Deviation) Units: years	73.7 (8.8)	74.4 (7.7)	74.1 (8.3)
Gender, Male/Female Measure Type: Number Units: participants			

Female	83	75	158
Male	50	69	119
Controlled Oral Word Association Test (COWAT): Baseline Efficacy Scores [1] Mean (Standard Deviation) Units: Number of words	19.7 (10.3)	19.2 (8.8)	19.4 (9.6)
	[1] COWAT: Verbal fluency test. The patient was asked to, during 1 minute, generate as many words as possible beginning with three pre-specified letters. The total score was calculated as the sum of acceptable words generated, with higher scores indicating lower cognitive impairment.		
Category Fluency Test (CFT): Baseline Efficacy Scores [1] Mean (Standard Deviation) Units: Number of words	13.5 (5.8)	13.3 (5.9)	13.4 (5.9)
	[1] CFT: The patient was asked to, during 1 minute, say aloud as many different words as possible from the categories animals and fruits. The total score was calculated as the number of appropriate words generated, with higher scores indicating lower cognitive impairment.		
ADAS-cog-Orientation Test (ADAS-cog-OT): Baseline Efficacy Scores [1] Mean (Standard Deviation) Units: Points	4.2 (1.6)	4.0 (1.7)	4.1 (1.7)
	[1] ADAS-cog-OT: A subscale of the ADAS-cog test with 8 questions and designed to determine how well oriented the patient is with regard to time and place. The total score was calculated as 8 minus the total number of correct answers, with higher scores indicating greater cognitive impairment.		
Stroop Interference Test - Incongruent (SIT-I): Baseline Efficacy Scores [1] Mean (Standard Deviation) Units: Seconds	170.3 (60.4)	176.4 (56.7)	173.4 (58.5)
	[1] SIT-I: A test to demonstrate the reaction time. Names of colours are printed in a different ink than the colour named. The time taken to complete the test was recorded, as was the number of errors. The more time spent and the higher number of errors indicates lower reaction time.		
Stroop Interference Test - Congruent (SIT-C): Baseline Efficacy Scores [1] Mean (Standard Deviation) Units: Seconds	70.5 (49.1)	68.8 (41.7)	69.6 (45.4)
	[1] SIT-C: A test to demonstrate the reaction time. Names of colours are printed in the same ink as the colours named. The time taken to complete the test was recorded, as was the number of errors. The more time spent and the higher number of errors indicates lower reaction time.		
Mini Mental State			

Examination (MMSE): Baseline Efficacy Scores [1] Mean (Standard Deviation) Units: Points	16.9 (2.4)	17.0 (2.4)	16.9 (2.4)
	[1] MMSE: Brief, structured examination of mental status that assesses orientation, memory, attention, naming, comprehension, and praxis. The range is 0 to 30, with a lower score indicating a worse mental state.		
Neuropsychiatric Inventory (NPI): Baseline Efficacy Scores [1] Mean (Standard Deviation) Units: Points	13.1 (12.8)	12.8 (12.4)	13.0 (12.6)
	[1] NPI: A scale specifically developed to assess behavioural disturbances in patients with dementia. It is based on responses from the caregiver. The range is 0 to 120, with higher score reflecting higher frequency and severity of the disturbances.		
Magnetic Resonance Imaging (MRI) Descriptives Mean (Standard Deviation) Units: mL; mm^3			
Total Brain Volume (TBV)	957.9 (103.3)	968.9 (108.3)	963.6 (105.8)
Hippocampal Volume (HCV)	5063.0 (1014.3)	5107.6 (836.7)	5086.1 (924.9)

Outcome Measures

1. Primary Outcome

Title:	Total Brain Atrophy Rate Estimated Using Brain Boundary Shift Integral (BBSI)
Description:	Measures direct changes in total brain volume per visit interval (screening to Week 4, 42, or 52 or from Week 4 to Week 42 or 52)
Time Frame:	Baseline to 1 year
Safety Issue?	No

Outcome Measure Data 2 Notes

Analysis Population Description

FAS-MRI: Full-analysis set for all patients in the all-patients-treated set (APTS) who had at least one valid MRI scan >=6 months after initiation of investigational medicinal product (IMP). The FAS (full analysis set, efficacy set) replaces the intention-to-treat (ITT) concept used in older terminology.

Arm/Group Title	Memantine 10 mg Tablets	Placebo Tablets Twice Daily

	Twice Daily	
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	110	118
Mean (Standard Error) Units: mL/year	15.24 (0.97)	15.32 (0.91)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Groups	Memantine 10 mg Tablets Twice Daily, Placebo Tablets Twice Daily
	Comments	Linear mixed model relating direct change in brain volume (BBSI) to time and its interaction with treatment group. This model additionally includes a time-by-AChEI group interaction as a fixed effect.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical	P-Value	0.9754

Test of Hypothesis	Comments	[Not specified]
	Method	Mixed Models Analysis
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other[Adjusted mean difference]
	Estimated Value	-0.04
	Confidence Interval	(2-Sided) 95% -2.60 to 2.52
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.30
	Estimation Comments	[Not specified]

2. Secondary Outcome

Title:	Changes in Total Hippocampal Volume (HCV)
▼ Description:	Estimated mean changes in total HCV NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.
Time Frame:	Baseline to 1 year
Safety Issue?	No

▼ Outcome Measure Data ✓ 2 Notes

▼ Analysis Population Description

FAS-MRI

Arm/Group Title	Memantine 10 mg Tablets Twice Daily	Placebo Tablets Twice Daily
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	95	109
Mean (Standard Deviation) Units: mm^3/year	-218 (182)	-220 (171)

▼ Statistical Analysis 1 ✓

Statistical	Comparison Groups	Memantine 10 mg Tablets Twice

Analysis Overview		Daily, Placebo Tablets Twice Daily
	Comments	Mixed model repeated measurements (MMRM) with unstructured covariance including time, time-by-treatment, visit, pre-treatment HCV, and AChEI group.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.842
	Comments	[Not specified]
	Method	Other [MMRM]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other[Adjusted mean difference]
	Estimated Value	-3.50
	Confidence Interval	(2-Sided) 95% -38.04 to 31.04
	Parameter Dispersion	Type: Standard Error of the mean Value: 17.52
	Estimation Comments	[Not specified]

3. Secondary Outcome

Title:	Cognitive and Behavioural Outcomes: Controlled Oral Word Association Test (COWAT) Total Score
▼ Description:	Adjusted mean change from baseline on cognitive and behavioural scores. COWAT: Verbal fluency test. The patient was asked to, during 1 minute, generate as many words as possible beginning with three pre-specified letters. The total score was calculated as the sum of acceptable words generated, with higher scores indicating lower cognitive impairment
Time Frame:	Baseline to 1 year
Safety Issue?	No

▼ Outcome Measure Data ✔ 2 Notes

▼ Analysis Population Description
FAS, observed cases (OC)

Arm/Group Title	Memantine 10 mg Tablets Twice Daily	Placebo Tablets Twice Daily
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	106	114
Least Squares Mean (Standard Error) Units: Scale scores	0.78 (0.71)	-0.90 (0.69)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Memantine 10 mg Tablets Twice Daily, Placebo Tablets Twice Daily
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.034
	Comments	The p-value represents the difference from placebo for COWAT at Week 52 (MMRM).
	Method	Other [MMRM]

	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	1.68
	Confidence Interval	(2-Sided) 95% 0.13 to 3.23
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.79
	Estimation Comments	[Not specified]

4. Secondary Outcome

Title:	Cognitive and Behavioural Outcomes: Mini Mental State Examination (MMSE) Total Score
▼ Description:	Adjusted mean change from baseline on cognitive and behavioural scores. MMSE: Brief, structured examination of mental status that assesses orientation, memory, attention, naming, comprehension, and praxis. The range is 0 to 30, with a lower score indicating a worse mental state
Time Frame:	Baseline to 1 year
Safety Issue?	No

▼ Outcome Measure Data ✔ 2 Notes

▼ Analysis Population Description

FAS, OC

Arm/Group Title	Memantine 10 mg Tablets Twice Daily	Placebo Tablets Twice Daily
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	108	114
Least Squares Mean (Standard Error) Units: Scale scores	-0.50 (0.45)	-0.74 (0.44)

▼ Statistical Analysis 1 ✔

Statistical Analysis	Comparison Groups	Memantine 10 mg Tablets Twice Daily, Placebo Tablets Twice Daily

Overview		
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.602
	Comments	The p-value represents the difference from placebo for MMSE at Week 52 (MMRM).
	Method	Other [MMRM]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.24
	Confidence Interval	(2-Sided) 95% -0.67 to 1.15
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.46
	Estimation Comments	[Not specified]

Adverse Events

Time Frame	1 year	
Additional Description		
Source Vocabulary Name	MedDRA (11.1)	
Assessment Type	Systematic Assessment	
Arm/Group Title	Memantine 10 mg Tablets Twice Daily	Placebo Tablets Twice Daily
Arm/Group Description	[Not specified] NOTE : An entry in Arm/Group Description is recommended.	[Not specified] NOTE : An entry in Arm/Group Description is recommended.

Serious Adverse Events

	Memantine 10 mg Tablets Twice Daily	Placebo Tablets Twice Daily

	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	17/133 (12.78%)		20/144 (13.89%)	
Blood and lymphatic system disorders				
Anaemia † A	1/133 (0.75%)	1	0/144 (0%)	0
Cardiac disorders				
Angina pectoris † A	0/133 (0%)	0	1/144 (0.69%)	1
Atrial fibrillation † A	3/133 (2.26%)	5	0/144 (0%)	0
Cardiac failure † A	1/133 (0.75%)	1	0/144 (0%)	0
Sick sinus syndrome † A	0/133 (0%)	0	1/144 (0.69%)	1
Sinoatrial block † A	0/133 (0%)	0	1/144 (0.69%)	1
Gastrointestinal disorders				
Diverticulum intestinal haemorrhagic † A	1/133 (0.75%)	1	0/144 (0%)	0
Intestinal obstruction † A	0/133 (0%)	0	1/144 (0.69%)	1
Subileus † A	0/133 (0%)	0	1/144 (0.69%)	1
Infections and infestations				
Bronchitis † A	0/133 (0%)	0	1/144 (0.69%)	1
Lower respiratory tract infection † A	0/133 (0%)	0	1/144 (0.69%)	1
Urinary tract infection † A	1/133 (0.75%)	1	0/144 (0%)	0
Injury, poisoning and procedural complications				
Ankle fracture † A	1/133 (0.75%)	1	0/144 (0%)	0
Cervical vertebral fracture † A	1/133 (0.75%)	1	0/144 (0%)	0
Contusion † A	1/133 (0.75%)	1	0/144 (0%)	0
Fall † A	4/133 (3.01%)	4	8/144 (5.56%)	9
Femoral neck fracture † A	0/133 (0%)	0	3/144 (2.08%)	3
Gastrointestinal stoma complication † A	1/133 (0.75%)	1	0/144 (0%)	0
Hip fracture † A	0/133 (0%)	0	1/144 (0.69%)	1
Humerus fracture † A	0/133 (0%)	0	1/144 (0.69%)	1
Pelvic fracture † A	1/133 (0.75%)	1	0/144 (0%)	0
Radius fracture † A	0/133 (0%)	0	1/144 (0.69%)	1
Rib fracture † A	1/133 (0.75%)	1	0/144 (0%)	0
Road traffic accident † A	1/133 (0.75%)	1	0/144 (0%)	0
Thoracic vertebral fracture † A	1/133 (0.75%)	1	0/144 (0%)	0
Metabolism and nutrition disorders				
Hypoglycaemia † A	0/133 (0%)	0	1/144 (0.69%)	1
Neoplasms benign, malignant and unspecified (incl cysts				

and polps)				
Gastrointestinal cancer metastatic † A	1/133 (0.75%)	1	0/144 (0%)	0
Prostate cancer [gs] † A	1/133 (0.75%)	1	0/144 (0%)	0
Nervous system disorders				
Balance disorder † A	1/133 (0.75%)	1	0/144 (0%)	0
Cerebral haemorrhage † A	1/133 (0.75%)	1	0/144 (0%)	0
Cerebral infarction † A	1/133 (0.75%)	1	0/144 (0%)	0
Cerebrovascular accident † A	1/133 (0.75%)	1	0/144 (0%)	0
Convulsion † A	0/133 (0%)	0	1/144 (0.69%)	1
Dementia † A	1/133 (0.75%)	1	0/144 (0%)	0
Lacunar infarction † A	1/133 (0.75%)	1	0/144 (0%)	0
Partial seizures † A	0/133 (0%)	0	1/144 (0.69%)	1
Somnolence † A	0/133 (0%)	0	1/144 (0.69%)	1
Syncope † A	0/133 (0%)	0	1/144 (0.69%)	1
Transient ischaemic attack † A	1/133 (0.75%)	1	1/144 (0.69%)	1
Psychiatric disorders				
Abnormal behaviour † A	1/133 (0.75%)	1	0/144 (0%)	0
Agitation † A	1/133 (0.75%)	1	1/144 (0.69%)	1
Delirium † A	0/133 (0%)	0	1/144 (0.69%)	1
Delusion † A	1/133 (0.75%)	1	0/144 (0%)	0
Disorientation † A	1/133 (0.75%)	1	0/144 (0%)	0
Hallucination † A	1/133 (0.75%)	1	0/144 (0%)	0
Insomnia † A	1/133 (0.75%)	1	0/144 (0%)	0
Paranoia † A	1/133 (0.75%)	1	0/144 (0%)	0
Renal and urinary disorders				
Renal failure acute † A	0/133 (0%)	0	1/144 (0.69%)	1
Urinary incontinence † A	0/133 (0%)	0	1/144 (0.69%)	1
Reproductive system and breast disorders				
Benign prostatic hyperplasia [gs] † A	0/133 (0%)	0	1/144 (0.69%)	1
Respiratory, thoracic and mediastinal disorders				
Haemothorax † A	1/133 (0.75%)	1	0/144 (0%)	0
Social circumstances				
Social stay hospitalisation † A	1/133 (0.75%)	1	0/144 (0%)	0
Surgical and medical procedures				
Knee arthroplasty † A	0/133 (0%)	0	1/144 (0.69%)	1
Pacemaker generated rhythm † A	1/133 (0.75%)	1	0/144 (0%)	0

Vascular disorders				
Aortic aneurysm rupture † A	0/133 (0%)	0	1/144 (0.69%)	1
Circulatory collapse † A	1/133 (0.75%)	1	0/144 (0%)	0
Hypotension † A	0/133 (0%)	0	2/144 (1.39%)	2

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%			
	Memantine 10 mg Tablets Twice Daily		**Placebo Tablets Twice Daily**	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	46/133 (34.59%)		36/144 (25%)	
Gastrointestinal disorders				
Diarrhoea † A	4/133 (3.01%)	5	10/144 (6.94%)	11
Infections and infestations				
Urinary tract infection † A	7/133 (5.26%)	8	5/144 (3.47%)	8
Injury, poisoning and procedural complications				
Fall † A	8/133 (6.02%)	9	9/144 (6.25%)	10
Nervous system disorders				
Dizziness † A	11/133 (8.27%)	11	4/144 (2.78%)	8
Headache † A	9/133 (6.77%)	11	7/144 (4.86%)	8
Psychiatric disorders				
Agitation † A	7/133 (5.26%)	7	1/144 (0.69%)	1

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents)

that restricts the PI's rights to discuss or publish trial results after the trial is completed. Publication of the results by the Investigator will be subject to mutual agreement between the Investigator and H. Lundbeck A/S. Manuscripts and abstracts must be sent to H. Lundbeck A/S at least one month prior to submission for publication or presentation.

Results Point of Contact

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Close