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Trial record **1 of 1** for: GALALZ3005

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A Study of Galantamine Used to Treat Patients With Mild to Moderate Alzheimer's Disease

This study has been terminated.

(Due to a pre-specified imbalance of deaths between treatment groups, the DSMB recommended early termination of the trial)

Sponsor:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
Janssen Research & Development, LLC

ClinicalTrials.gov Identifier:
NCT00679627

First received: May 15, 2008
Last updated: September 10, 2013
Last verified: September 2013
History of Changes

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Results First Received: April 23, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Alzheimer's Disease
Interventions:	Drug: Galantamine 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
This study investigated the benefits and risks of long-term galantamine use in participants with Alzheimer's Disease. The study was conducted from 19 May 2008 to 20 May 2012 at 127 clinical centers in 13 countries. A total of 2051 participants were randomized to study treatment, of these 2045 received at least 1 dose of treatment.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
The Data Safety Monitoring Board (DSMB) recommended that the study be terminated early because of an imbalance of deaths between the treatment groups.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the

	first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Participant Flow: Overall Study

	Placebo	Galantamine
STARTED	1021	1024
COMPLETED	322	339
NOT COMPLETED	699	685
Death	41	29
Adverse Event	43	53
Withdrawal by Subject	168	172
Lost to Follow-up	22	26
Early Study Closure	425	405

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
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Galantamine	Total
Number of Participants [units: participants]	1021	1024	2045
Age [units: participants] Mean (Standard Deviation)	73.2 (8.67)	73 (8.88)	73.1 (8.77)
Age, Customized [units: participants]			
<61	112	112	224
61-<76	467	466	933
>=76	442	446	888

Gender [units: participants]			
Female	**654**	**671**	**1325**
Male	**367**	**353**	**720**
Region of Enrollment [units: participants]			
Czech Republic	**33**	**34**	**67**
Estonia	**53**	**51**	**104**
France	**10**	**11**	**21**
Germany	**218**	**221**	**439**
Greece	**35**	**36**	**71**
Italy	**25**	**24**	**49**
Latvia	**2**	**2**	**4**
Lithuania	**23**	**21**	**44**
Romania	**84**	**84**	**168**
Russia	**274**	**271**	**545**
Slovakia	**85**	**88**	**173**
Slovenia	**13**	**13**	**26**
Ukraine	**166**	**168**	**334**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in the Mini–Mental State Examination (MMSE) Score [Time Frame: Baseline, Month 24]

Measure Type	Primary
Measure Title	Change From Baseline in the Mini–Mental State Examination (MMSE) Score
Measure Description	The MMSE is a brief 30-point questionnaire test that is used or the assessment of dementia patients' cognitive impairment. Evaluation of points are as follows: 24 to 30 = no cognitive impairment, 18 to 23 = mild cognitive impairment, 0 to 17 = severe cognitive impairment. Lower scores indicate worsening.
Time Frame	Baseline, Month 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.
An intent-to-treat (ITT) with last observation carried forward (LOCF) approach was used for the primary analysis. The ITT analysis set included all randomized participants who received at least 1 dose of treatment and had at least 1 postbaseline MMSE measure.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During

	the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	Galantamine
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in the Mini–Mental State Examination (MMSE) Score [units: Scores on scale] Mean (Standard Deviation)	**-2.14 (4.340)**	**-1.41 (4.050)**

Statistical Analysis 1 for Change From Baseline in the Mini–Mental State Examination (MMSE) Score

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[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.

2. Primary: The Number of Deaths Reported in Participants [Time Frame: Up to 2 years]

Measure Type	Primary
Measure Title	The Number of Deaths Reported in Participants
Measure Description	An external Data Safety Monitoring Board (DSMB) was assigned for this study to monitor the progress of the study and to ensure that the safety of participants was not compromised.
Time Frame	Up to 2 years
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 analysis was performed on the safety population, ie, all randomized participants who received at least one dose of the study drug.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of

	the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	Galantamine
Number of Participants Analyzed [units: participants]	**1021**	**1024**
The Number of Deaths Reported in Participants [units: Number of Participants]	**56**	**33**

Statistical Analysis 1 for The Number of Deaths Reported in Participants

Groups [1]	All groups
Method [2]	Regression, Cox
P Value [3]	0.011
Hazard Ratio (HR) [4]	0.58
95% Confidence Interval	0.37 to 0.89

[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.

3. Secondary: Change From Baseline in the Mini–Mental State Examination (MMSE) Score [Time Frame: Baseline, Month 6]

Measure Type	Secondary
Measure Title	Change From Baseline in the Mini–Mental State Examination (MMSE) Score
Measure Description	The MMSE is a brief 30-point questionnaire test that is used or the assessment of dementia patients' cognitive impairment. Evaluation of points are as follows: 24 to 30 = no cognitive impairment, 18 to 23 = mild cognitive impairment, 0 to 17 = severe cognitive impairment. Lower scores indicate worsening.
Time Frame	Baseline, Month 6
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.
An intent-to-treat (ITT) with last observation carried forward (LOCF) approach was used for the primary analysis. The ITT analysis set included all randomized participants who received at least 1 dose of treatment and had at least 1 postbaseline MMSE measure.

Reporting Groups

	Description

Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	Galantamine
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in the Mini–Mental State Examination (MMSE) Score [units: Scores on scale] Mean (Standard Deviation)	**-0.28 (2.938)**	**0.15 (2.725)**

Statistical Analysis 1 for Change From Baseline in the Mini–Mental State Examination (MMSE) Score

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[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. Secondary: Change From Baseline in Disability Assessment in Dementia (DAD) Scores [Time Frame: Baseline, Month 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Disability Assessment in Dementia (DAD) Scores
Measure Description	The DAD assesses physical activities of daily living and instrumental-activities of daily livings of participants with Alzheimer disease. This measure is a validated, disability assessment scale that collects information regarding the ability of a participant to initiate, plan, organize, and perform activities of daily living, as based on a structured interview with the caregiver. The maximum scores were 13 for initiation, 10 for planning and organizing, and 17 for effective performance in order to yield a total maximum score of 40. These scores were normalized to a scale of 100 for analysis.A higher score, or percentage of items that can be performed represents fewer disabilities in carrying out activities of daily living while a lower percentage indicates an increase in disabilities.
Time Frame	Baseline, Month 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.
An intent-to-treat (ITT) with last observation carried forward (LOCF) approach was used for the analysis. The ITT analysis set included all

randomized participants who received at least 1 dose of treatment and had at least 1 postbaseline DAD measure.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	Galantamine
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in Disability Assessment in Dementia (DAD) Scores [units: Scores on scale] Mean (Standard Deviation)	**-10.81 (18.268)**	**-8.16 (17.251)**

Statistical Analysis 1 for Change From Baseline in Disability Assessment in Dementia (DAD) Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.002

[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.

5. Secondary: Change From Baseline in Patient Accommodation Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB) [Time Frame: Baseline, Months 12 and 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Patient Accommodation Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB)
Measure Description	The APAS-CarB is a measure used to evaluate participant status and caregiver burden. The table below presents Patient Accommodation assessed as the percentage of participants "home with friend or relative" using the APAS-CarB.
Time Frame	Baseline, Months 12 and 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.
An intent-to-treat (ITT) with last observation carried forward (LOCF) approach was used for the analysis. The ITT analysis set included all randomized participants who received at least 1 dose of treatment and had at least 1 postbaseline APAS-CarB measure.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	**Galantamine**
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in Patient Accommodation Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB) [units: Percentage of participants]		
Home with friend or relative - Baseline	**62.1**	**62.8**
Home with friend or relative - Month 12	**61.4**	**61.8**
Home with friend or relative - Month 24	**55.3**	**60.1**

No statistical analysis provided for Change From Baseline in Patient Accommodation Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB)

6. Secondary: Change From Baseline in Caregiver Time Spent With the Patient Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB) [Time Frame: Baseline, Months 12 and 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Caregiver Time Spent With the Patient Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB)
Measure Description	The table below presents the number of days that caregiving activities were provided during the past week.
Time Frame	Baseline, Months 12 and 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 ITT analysis set included all randomized participants who received at least 1 dose of treatment and had at least 1 postbaseline measure.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine

	capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	**Galantamine**
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in Caregiver Time Spent With the Patient Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB) [units: Days] Mean (Standard Deviation)		
Provided caregiving during past week - Baseline	**5.91 (2.094)**	**5.77 (2.241)**
Provided caregiving during past week - Month 12	**6.06 (1.964)**	**6.07 (1.969)**
Provided caregiving during past week - Month 24	**6.13 (1.952)**	**6.20 (1.830)**

No statistical analysis provided for Change From Baseline in Caregiver Time Spent With the Patient Measured Using the Assessment of Subject Accommodation Status and Caregiver Burden (APAS-CarB)

7. Secondary: Change From Baseline in Institutional Status [Time Frame: Baseline, Month 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Institutional Status
Measure Description	This table describes the number of participants who were reported as institutionalized at baseline and Month 24.
Time Frame	Baseline, Month 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 ITT analysis set included all randomized participants who received at least 1 dose of treatment and had at least 1 postbaseline measure.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	Galantamine
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in Institutional Status [units: Number of Participants]		
Baseline	**1**	**0**
Month 24	**5**	**6**

Statistical Analysis 1 for Change From Baseline in Institutional Status

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.269

[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:
	Baseline

Statistical Analysis 2 for Change From Baseline in Institutional Status

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.835

[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:
	Month 24

8. Secondary: Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language) [Time Frame: Baseline, Month 24]

Measure Type	Secondary
Measure Title	Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language)
Measure Description	The MMSE, is a validated, brief examination that rates subjects on orientation (total score, 10), registration (total score, 3), attention (total score, 5), calculation (total score, 5), recall (total score, 3), and language (total score, 9). The maximum score is 30 (only the higher of the two scores for attention and calculation [each with a maximum score of 5]

	was used). A higher score compared with baseline indicates less impairment.
Time Frame	Baseline, Month 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 ITT analysis set included all randomized participants who received at least 1 dose of treatment and had at least 1 postbaseline MMSE measure.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	**Galantamine**
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language) [units: Scores on scale] Mean (Standard Deviation)		
Orientation	**-0.96 (2.320)**	**-0.76 (2.128)**
Registration	**-0.20 (0.771)**	**-0.16 (0.692)**
Attention and Calculation	**-0.46 (1.526)**	**-0.16 (1.561)**
Recall	**0.00 (1.013)**	**0.10 (1.070)**
Language	**-0.93 (1.895)**	**-0.68 (1.867)**

Statistical Analysis 1 for Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.194

[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:
	Orientation subscale

Statistical Analysis 2 for Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.353

[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:
	Registration subscale

Statistical Analysis 3 for Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.009

[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:
	Attention and Calculation subscale

Statistical Analysis 4 for Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.158

[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:
	Recall subscale

Statistical Analysis 5 for Change From Baseline in the Mini–Mental State Examination (MMSE) Subscales (Orientation, Registration, Attention and Calculation, Recall, and Language)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.088

[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:
	Language subscale

9. Secondary: Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure) [Time Frame: Baseline, Month 24]

Measure Type	Secondary
Measure Title	Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure)
Measure Description	The DAD assesses physical activities of daily living and instrumental-activities of daily livings of participants with Alzheimer disease. This measure is a validated, disability assessment scale that collects information regarding the ability of a participant to initiate, plan, organize, and perform activities of daily living, as based on a structured interview with the caregiver. The maximum scores were 13 for initiation, 10 for planning and organizing, and 17 for effective performance in order to yield a total maximum score of 40. These scores were normalized to a scale of 100 for analysis.A higher score, or percentage of items that can be performed represents fewer disabilities in carrying out activities of daily living while a lower percentage indicates an increase in disabilities.
Time Frame	Baseline, Month 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.
This analysis was performed in the intent-to-treat population which included all randomized participants who had at least 1 postbaseline DAD measure.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Measured Values

	Placebo	Galantamine
Number of Participants Analyzed [units: participants]	**906**	**906**
Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure) [units: Scores on scale] Mean (Standard Deviation)		
Initiation	**-13.53 (22.993)**	**-9.60 (20.660)**
Planning and Organization	**-13.14 (24.565)**	**-9.96 (23.154)**
Effective Performance	**-13.82 (21.975)**	**-10.82 (19.959)**
Basic	**-14.24 (24.093)**	**-9.84 (21.899)**
Instrumental	**-13.52 (23.210)**	**-10.72 (21.714)**
Leisure	**-13.02 (35.370)**	**-10.46 (32.769)**

Statistical Analysis 1 for Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.010

[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:
	Initiation subscale

Statistical Analysis 2 for Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.043

[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:
	Planning and Organization subscale

Statistical Analysis 3 for Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.018

[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:
	Effective Performance subscale

Statistical Analysis 4 for Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.005

[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:
	Basic subscale

Statistical Analysis 5 for Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.054

[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:
	Instrumental subscale

Statistical Analysis 6 for Change From Baseline in the Disability Assessment in Dementia (DAD) Subscales (Initiation, Planning and Organization, Effective Performance, Basic, Instrumental, and Leisure)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.137

[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:
	Leisure subscale

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Over 2 years
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Serious Adverse Events

	Placebo	Galantamine
Total, serious adverse events		
# participants affected / at risk	**123/1021 (12.05%)**	**129/1024 (12.60%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Cardiac disorders		
Acute Myocardial Infarction * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**1/1024 (0.10%)**
Arrhythmia * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Arteriosclerosis Coronary Artery * 1		

# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Atrial Fibrillation [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Bradyarrhythmia [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Bradycardia [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Cardiac Arrest [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Cardiac Failure [*1]		
# participants affected / at risk	3/1021 (0.29%)	10/1024 (0.98%)
Cardiac Failure Acute [*1]		
# participants affected / at risk	2/1021 (0.20%)	2/1024 (0.20%)
Cardio-Respiratory Arrest [*1]		
# participants affected / at risk	3/1021 (0.29%)	0/1024 (0.00%)
Cardiopulmonary Failure [*1]		
# participants affected / at risk	4/1021 (0.39%)	3/1024 (0.29%)
Cardiovascular Insufficiency [*1]		
# participants affected / at risk	3/1021 (0.29%)	1/1024 (0.10%)
Ischaemic Cardiomyopathy [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Myocardial Infarction [*1]		
# participants affected / at risk	2/1021 (0.20%)	6/1024 (0.59%)
Myocardial Ischaemia [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Postinfarction Angina [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Tachyarrhythmia [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Ear and labyrinth disorders		
Vertigo [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Eye disorders		
Cataract [*1]		
# participants affected / at risk	0/1021 (0.00%)	2/1024 (0.20%)
Cataract Subcapsular [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Glaucoma [*1]		
# participants affected / at risk	0/1021 (0.00%)	2/1024 (0.20%)
Lens Disorder [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Gastrointestinal disorders		
Anal Polyp [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)

Colitis Ischaemic [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Diarrhoea [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Duodenal Ulcer Perforation [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Dysphagia [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Enterocolitis [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Enterocolitis Haemorrhagic [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Faecal Incontinence [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Gastric Ulcer [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Gastric Ulcer Haemorrhage [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Gastroduodenitis [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**2/1024 (0.20%)**
Haemorrhagic Erosive Gastritis [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Haemorrhoidal Haemorrhage [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Haemorrhoids [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Ileus [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Inguinal Hernia [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**2/1024 (0.20%)**
Intestinal Stenosis [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Nausea [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Oesophageal Achalasia [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Pancreatitis [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Peritoneal Haemorrhage [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Upper Gastrointestinal Haemorrhage [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Varices Oesophageal [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**

Vomiting [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
General disorders		
Abasia [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Death [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Hypothermia [*1]		
# participants affected / at risk	2/1021 (0.20%)	0/1024 (0.00%)
Inflammation [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Multi-Organ Failure [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Oedema Peripheral [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Pyrexia [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Sudden Death [*1]		
# participants affected / at risk	3/1021 (0.29%)	1/1024 (0.10%)
Hepatobiliary disorders		
Bile Duct Stone [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Cholecystitis [*1]		
# participants affected / at risk	1/1021 (0.10%)	2/1024 (0.20%)
Infections and infestations		
Abscess [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Bronchitis [*1]		
# participants affected / at risk	0/1021 (0.00%)	2/1024 (0.20%)
Bronchopneumonia [*1]		
# participants affected / at risk	3/1021 (0.29%)	2/1024 (0.20%)
Clostridium Difficile Colitis [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Ear Infection [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Gastroenteritis Rotavirus [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Gastrointestinal Infection [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Herpes Zoster [*1]		
# participants affected / at risk	1/1021 (0.10%)	2/1024 (0.20%)
Peritonitis [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Pneumonia [*1]		

# participants affected / at risk	6/1021 (0.59%)	8/1024 (0.78%)
Post Procedural Infection [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Sepsis [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Tuberculosis [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Urinary Tract Infection [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Urosepsis [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Injury, poisoning and procedural complications		
Accidental Overdose [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Carbon Monoxide Poisoning [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Chemical Poisoning [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Exposure to Toxic Agent [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Fall [*1]		
# participants affected / at risk	3/1021 (0.29%)	2/1024 (0.20%)
Femoral Neck Fracture [*1]		
# participants affected / at risk	3/1021 (0.29%)	2/1024 (0.20%)
Femur Fracture [*1]		
# participants affected / at risk	3/1021 (0.29%)	3/1024 (0.29%)
Forearm Fracture [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Hand Fracture [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Head Injury [*1]		
# participants affected / at risk	2/1021 (0.20%)	1/1024 (0.10%)
Hip Fracture [*1]		
# participants affected / at risk	3/1021 (0.29%)	1/1024 (0.10%)
Humerus Fracture [*1]		
# participants affected / at risk	1/1021 (0.10%)	2/1024 (0.20%)
Injury [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Joint Dislocation [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Lower Limb Fracture [*1]		
# participants affected / at risk	0/1021 (0.00%)	2/1024 (0.20%)
Lumbar Vertebral Fracture [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)

Multiple Fractures [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Patella Fracture [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Rib Fracture [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Skeletal Injury [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Spinal Fracture [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Subdural Haematoma [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Subdural Haemorrhage [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Upper Limb Fracture [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Urethral Injury [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Wound Haemorrhage [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Investigations		
Blood Pressure Increased [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Weight Decreased [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Metabolism and nutrition disorders		
Decreased Appetite [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Dehydration [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**4/1024 (0.39%)**
Diabetes Mellitus [*1]		
# participants affected / at risk	**2/1021 (0.20%)**	**2/1024 (0.20%)**
Hyperglycaemia [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Musculoskeletal and connective tissue disorders		
Back Pain [*1]		
# participants affected / at risk	**2/1021 (0.20%)**	**1/1024 (0.10%)**
Bone Pain [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Intervertebral Disc Compression [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Muscular Weakness [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Musculoskeletal Pain [*1]		

# participants affected / at risk	2/1021 (0.20%)	1/1024 (0.10%)
Osteoarthritis [*1]		
# participants affected / at risk	0/1021 (0.00%)	2/1024 (0.20%)
Spinal Column Stenosis [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Spinal Osteoarthritis [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Adenocarcinoma Pancreas [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Breast Cancer [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Colon Cancer [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Hepatic Neoplasm Malignant [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Pancreatic Neoplasm [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Pharyngeal Neoplasm [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Prostatic Adenoma [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Rectal Cancer [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Salivary Gland Adenoma [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Nervous system disorders		
Altered State of Consciousness [*1]		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Cerebral Arteriosclerosis [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Cerebral Haemorrhage [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Cerebral Infarction [*1]		
# participants affected / at risk	2/1021 (0.20%)	1/1024 (0.10%)
Cerebrovascular Accident [*1]		
# participants affected / at risk	2/1021 (0.20%)	4/1024 (0.39%)
Cerebrovascular Disorder [*1]		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Coma [*1]		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Dementia [*1]		
# participants affected / at risk	2/1021 (0.20%)	0/1024 (0.00%)
Dementia Alzheimer's Type [*1]		

# participants affected / at risk	12/1021 (1.18%)	9/1024 (0.88%)
Diabetic Neuropathy * 1		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Epilepsy * 1		
# participants affected / at risk	3/1021 (0.29%)	0/1024 (0.00%)
Haemorrhage Intracranial * 1		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Haemorrhagic Stroke * 1		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Ischaemic Stroke * 1		
# participants affected / at risk	8/1021 (0.78%)	2/1024 (0.20%)
Loss of Consciousness * 1		
# participants affected / at risk	1/1021 (0.10%)	3/1024 (0.29%)
Polyneuropathy * 1		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Presyncope * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Speech Disorder * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Syncope * 1		
# participants affected / at risk	3/1021 (0.29%)	3/1024 (0.29%)
Transient Ischaemic Attack * 1		
# participants affected / at risk	3/1021 (0.29%)	2/1024 (0.20%)
Vertebrobasilar Insufficiency * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Psychiatric disorders		
Abnormal Behaviour * 1		
# participants affected / at risk	1/1021 (0.10%)	0/1024 (0.00%)
Adjustment Disorder * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Aggression * 1		
# participants affected / at risk	1/1021 (0.10%)	3/1024 (0.29%)
Agitation * 1		
# participants affected / at risk	2/1021 (0.20%)	1/1024 (0.10%)
Catatonia * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Confusional State * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Delirium * 1		
# participants affected / at risk	1/1021 (0.10%)	1/1024 (0.10%)
Depression * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)
Disorientation * 1		
# participants affected / at risk	0/1021 (0.00%)	1/1024 (0.10%)

Psychotic Disorder [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**2/1024 (0.20%)**
Restlessness [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Suicide Attempt [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Renal and urinary disorders		
Incontinence [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Nephritis [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Renal Failure Acute [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Renal Failure Chronic [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Stress Urinary Incontinence [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Tubulointerstitial Nephritis [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Urinary Incontinence [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Urinary Retention [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**1/1024 (0.10%)**
Reproductive system and breast disorders		
Benign Prostatic Hyperplasia [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**2/1024 (0.20%)**
Pelvic Pain [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Scrotal Disorder [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Vulval Leukoplakia [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Acute Lung Injury [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Aspiration [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Bronchitis Chronic [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Chronic Obstructive Pulmonary Disease [*1]		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Dyspnoea [*1]		
# participants affected / at risk	**1/1021 (0.10%)**	**2/1024 (0.20%)**
Emphysema [*1]		

# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Pneumonia Aspiration * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Pneumothorax * 1		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Pulmonary Embolism * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**5/1024 (0.49%)**
Pulmonary Oedema * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Respiratory Failure * 1		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Skin and subcutaneous tissue disorders		
Decubitus Ulcer * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Psoriasis * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Rash * 1		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Surgical and medical procedures		
Carotid Artery Stent Removal * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Vascular disorders		
Arteriosclerosis * 1		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Circulatory Collapse * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Essential Hypertension * 1		
# participants affected / at risk	**0/1021 (0.00%)**	**2/1024 (0.20%)**
Haemorrhagic Infarction * 1		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Hypertension * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**1/1024 (0.10%)**
Hypertensive Crisis * 1		
# participants affected / at risk	**0/1021 (0.00%)**	**1/1024 (0.10%)**
Hypotension * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Malignant Hypertension * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**1/1024 (0.10%)**
Pallor * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**
Peripheral Arterial Occlusive Disease * 1		
# participants affected / at risk	**1/1021 (0.10%)**	**0/1024 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Over 2 years
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	During the titration and long-term maintenance periods, placebo was supplied as oral capsules matching galantamine capsules in size and appearance. The study drug was administered using the same titration and maintenance regimens as was used for participants in the galantamine treatment group.
Galantamine	During the titration period (Days 1 to 84), participants received galantamine controlled-release oral capsules 8 mg/day for the first 4 weeks, followed by 16 mg/day for the next 4 weeks, then 24 mg/day for the next 4 weeks (based on tolerability). During the long-term maintenance period (Months 4 to 24), participants received galantamine at the dosage achieved at Day 84 of the titration period and continued until the completion of the Month 24 visit. A one-time dose titration to 16 or 24 mg/day was allowed, based on the investigator's judgment and participant tolerability.

Other Adverse Events

	Placebo	Galantamine
Total, other (not including serious) adverse events		
# participants affected / at risk	**115/1021 (11.26%)**	**168/1024 (16.41%)**
Ear and labyrinth disorders		
Vertigo * 1		
# participants affected / at risk	**48/1021 (4.70%)**	**57/1024 (5.57%)**
Gastrointestinal disorders		
Nausea * 1		
# participants affected / at risk	**24/1021 (2.35%)**	**85/1024 (8.30%)**
Nervous system disorders		
Headache * 1		
# participants affected / at risk	**58/1021 (5.68%)**	**58/1024 (5.66%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 15.0

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
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:** If an investigator wishes to publish information from the study, a copy of the manuscript must be provided to the sponsor for review at least 60 days before submission for publication or presentation. If requested by the sponsor in writing, the investigator will withhold such publication for up to an additional 60 days to allow for filing of a patent application.

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Responsible Party:	Janssen Research & Development, LLC
ClinicalTrials.gov Identifier:	NCT00679627 History of Changes
Other Study ID Numbers:	CR012463 **GALALZ3005** (Other Identifier: Janssen Research & Development, LLC)
Study First Received:	May 15, 2008
Results First Received:	April 23, 2013
Last Updated:	September 10, 2013
Health Authority:	Germany: Ethics Commission Greece: National Organization of Medicines Austria: Ethikkommission Italy: National Monitoring Centre for Clinical Trials - Ministry of Health Latvia: State Agency of Medicines Lithuania: State Medicine Control Agency - Ministry of Health Portugal: National Pharmacy and Medicines Institute Romania: National Medicines Agency Slovakia: State Institute for Drug Control Slovenia: Agency for Medicinal Products - Ministry of Health Spain: Comité Ético de Investigación Clínica Spain: Spanish Agency of Medicines United Kingdom: Medicines and Healthcare Products Regulatory Agency United Kingdom: Research Ethics Committee Austria: Agency for Health and Food Safety Germany: Federal Institute for Drugs and Medical Devices France: Institutional Ethical Committee France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Estonia: The State Agency of Medicine Czech Republic: State Institute for Drug Control Italy: Ethics Committee Ukraine: State Pharmacological Center - Ministry of Health

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