Comparison of 23 mg Donepezil Sustained Release (SR) to 10 mg Donepezil Immediate Release (IR) in Patients With Moderate to Severe Alzheimer's Disease

This study has been completed.

Sponsor:
Eisai Inc.

Collaborator:
Eisai Limited

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT00478205

First received: May 22, 2007
Last updated: June 26, 2014
Last verified: January 2013
History of Changes

Results First Received: November 12, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Alzheimer's Disease
Interventions:	Drug: Aricept (donepezil SR 23 mg) Drug: Aricept (donepezil IR 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 SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing continued for a 24-week treatment period.

Participant Flow: Overall Study

	Donepezil SR 23 mg	Donepezil IR 10 mg
STARTED	**981**	**486**
COMPLETED	**685**	**399**
NOT COMPLETED	**296**	**87**
Adverse Event	**182**	**39**
Medication Non-compliance	**9**	**4**
Protocol Violation	**15**	**5**
Request of Investigator or Sponsor	**4**	**5**
Withdrawal by Subject	**61**	**22**
Lack of Efficacy	**1**	**0**
Not specified	**24**	**12**

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 SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing continued for a 24-week treatment period.
Total	Total of all reporting groups

Baseline Measures

	Donepezil SR 23 mg	Donepezil IR 10 mg	Total
Overall Participants Analyzed [Units: Participants]	**963**	**471**	**1434**
Age [1] [Units: Years] Mean (Standard Deviation)	**73.9 (8.53)**	**73.8 (8.56)**	**73.8 (8.53)**
[1] Safety Population			
Gender [1] [Units: Participants]			

Female	**607**	**294**	**901**
Male	**356**	**177**	**533**

[1] Safety Population: All patients randomized who took at least one dose of study medication and who had at least one postbaseline safety assessment.

Race/Ethnicity, Customized [1] [Units: Participants]			
Black	**22**	**9**	**31**
White	**708**	**346**	**1054**
Hispanic	**67**	**26**	**93**
Native American	**0**	**0**	**0**
Asian/Pacific	**161**	**87**	**248**
Other	**5**	**3**	**8**

[1] Race (Safety Population)

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline to Week 24 in SIB Total Score [Time Frame: Baseline and Week 24]

Measure Type	Primary
Measure Title	Change From Baseline to Week 24 in SIB Total Score
Measure Description	The SIB is an assessment of cognitive dysfunction across nine domains such as memory, language, and orientation. The score ranges from 0 (worst) to 100 (best). This outcome was calculated using the LOCF (last observation carried forward) method.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: All Randomized patients in Safety Population and Severe Impairment Battery (SIB) or Clinician Interview-Based Impression of Severity Plus Caregiver Input (CIBIS+) data available at Baseline and SIB or Clinician Interview-Based Impression of Change Plus caregiver Input (CIBIC+) data available post-Baseline; LOCF

Reporting Groups

	Description
Donepezil SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing continued for a 24-week treatment period.

Measured Values

	Donepezil SR 23 mg	**Donepezil IR 10 mg**
Participants Analyzed [Units: Participants]	**909**	**462**

Change From Baseline to Week 24 in SIB Total Score [Units: Scores on a scale] Least Squares Mean (Standard Error)	**2.6 (0.58)**	**0.4 (0.66)**

No statistical analysis provided for Change From Baseline to Week 24 in SIB Total Score

2. Primary: Overall Change From Baseline in Modified CIBIC+ to Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Primary
Measure Title	Overall Change From Baseline in Modified CIBIC+ to Week 24
Measure Description	The CIBIC+ is a rating scale derived from an interview with the patient and caregiver with an independent rater designed to measure several domains of patient function, such as mental/cognitive state, behavior, and activities of daily living. The scores range from 1 (marked improvement) to 7 (marked worsening).
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population, LOCF

Reporting Groups

	Description
Donepezil SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing continued for a 24-week treatment period.

Measured Values

	Donepezil SR 23 mg	**Donepezil IR 10 mg**
Participants Analyzed [Units: Participants]	**909**	**462**
Overall Change From Baseline in Modified CIBIC+ to Week 24 [Units: Scores on a scale] Mean (Standard Deviation)	**4.23 (1.07)**	**4.29 (1.07)**

No statistical analysis provided for Overall Change From Baseline in Modified CIBIC+ to Week 24

3. Secondary: Change From Baseline to Week 24 in ADCS-ADL Total Score [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 24 in ADCS-ADL Total Score
Measure Description	The ADCS-ADL (Alzhemier's Disease Cooperative Study-Activities of Daily Living) is a 19-item assessment scale used to measure a patient's basic functional abilities, such as walking, grooming, and bathing.Scores range from 0 to 54, with a higher score indicating greater functional ability.

Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population, LOCF

Reporting Groups

	Description
Donepezil SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing continued for a 24-week treatment period.

Measured Values

	Donepezil SR 23 mg	**Donepezil IR 10 mg**
Participants Analyzed [Units: Participants]	**909**	**462**
Change From Baseline to Week 24 in ADCS-ADL Total Score [Units: Scores on a scale] Mean (Standard Deviation)	**-1.2 (6.83)**	**-1.2 (6.78)**

No statistical analysis provided for Change From Baseline to Week 24 in ADCS-ADL Total Score

4. Secondary: Change From Baseline to Week 24 in MMSE Total Score [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 24 in MMSE Total Score
Measure Description	The MMSE (Mini-Mental State Examination) is a 30-item test that evaluates 5 domains of cognitive function (orientation to time and place, immediate and delayed recall, attention, calculation, and language). The scores range from 0 (most impaired) to 30 (no impaiment).
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population, LOCF

Reporting Groups

	Description
Donepezil SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing

	continued for a 24-week treatment period.

Measured Values

	Donepezil SR 23 mg	Donepezil IR 10 mg
Participants Analyzed [Units: Participants]	909	462
Change From Baseline to Week 24 in MMSE Total Score [Units: Scores on a scale] Mean (Standard Deviation)	0.6 (2.93)	0.4 (3.20)

No statistical analysis provided for Change From Baseline to Week 24 in MMSE Total Score

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	All adverse events (AEs) were recorded from the time of informed consent until after the Final Visit or Early Termination.
Additional Description	Serious adverse events (SAEs) were monitored through the termination visit and through 30 days after study drug discontinuation, whichever was longer.

Reporting Groups

	Description
Donepezil SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing continued for a 24-week treatment period.

Serious Adverse Events

	Donepezil SR 23 mg	Donepezil IR 10 mg
Total, serious adverse events		
# participants affected / at risk	80/963 (8.31%)	45/471 (9.55%)
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Leukocytosis † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cardiac disorders		
Acute coronary syndrome † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Acute myocardial infarction † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Angina pectoris † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Atrial fibrillation † 1		

# participants affected / at risk	4/963 (0.42%)	1/471 (0.21%)
Bradycardia † 1		
# participants affected / at risk	4/963 (0.42%)	0/471 (0.00%)
Cardiac failure † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Cardiac failure congestive † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cardio-respiratory arrest † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cardiopulmonary failure † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cardiovascular disorder † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Coronary artery occlusion † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Myocardial infarction † 1		
# participants affected / at risk	2/963 (0.21%)	1/471 (0.21%)
Myocardial ischaemia † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Tachycardia † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Ventricular tachycardia † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Eye disorders		
Diplopia † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Gastrointestinal disorders		
Abdominal discomfort † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Abdominal pain † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Diarrhoea † 1		
# participants affected / at risk	4/963 (0.42%)	0/471 (0.00%)
Diarrhoea haemorrhagic † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Dyspepsia † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Gastric ulcer haemorrhage † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Gastritis † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Haematochezia † 1		

# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Hiatus hernia † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Inguinal hernia † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Nausea † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Oesophageal ulcer † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Rectal haemorrhage † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Small intestinal obstruction † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Vomiting † 1		
# participants affected / at risk	3/963 (0.31%)	0/471 (0.00%)
General disorders		
Asthenia † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Drowning † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
General physical health deterioration † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Hypothermia † 1		
# participants affected / at risk	1/963 (0.10%)	2/471 (0.42%)
Irritability † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Pyrexia † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Hepatobiliary disorders		
Bile duct stenosis † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Bile duct stone † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cholangitis acute † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cholecystitis acute † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Cholecystitis chronic † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cholelithiasis † 1		
# participants affected / at risk	1/963 (0.10%)	1/471 (0.21%)
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cellulitis † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)

Diverticulitis † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Gastroenteritis † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Gastrointestinal infection † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Pneumonia † 1		
# participants affected / at risk	3/963 (0.31%)	3/471 (0.64%)
Sepsis † 1		
# participants affected / at risk	1/963 (0.10%)	1/471 (0.21%)
Septic shock † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Urinary tract infection † 1		
# participants affected / at risk	6/963 (0.62%)	2/471 (0.42%)
Injury, poisoning and procedural complications		
Burns first degree † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Burns second degree † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Contusion † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Facial bones fracture † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Fall † 1		
# participants affected / at risk	6/963 (0.62%)	2/471 (0.42%)
Femoral neck fracture † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Femur fracture † 1		
# participants affected / at risk	4/963 (0.42%)	1/471 (0.21%)
Hip fracture † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Neck injury † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Overdose † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Pelvic fracture † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Procedural complication † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Rib fracture † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Road traffic accident † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Skin laceration † 1		
# participants affected / at risk	1/963 (0.10%)	1/471 (0.21%)
Subdural haematoma † 1		

# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Upper limb fracture † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Wrist fracture † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Investigations		
Blood pressure increased † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Electrocardiogram QT prolonged † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Weight decreased † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Metabolism and nutrition disorders		
Anorexia † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Dehydration † 1		
# participants affected / at risk	3/963 (0.31%)	0/471 (0.00%)
Musculoskeletal and connective tissue disorders		
Arthritis † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Back pain † 1		
# participants affected / at risk	2/963 (0.21%)	1/471 (0.21%)
Mobility decreased † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Abdominal neoplasm † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Breast cancer † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Colon cancer † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Prostate cancer recurrent † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Nervous system disorders		
Balance disorder † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Cerebellar infarction † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Cerebrovascular accident † 1		
# participants affected / at risk	1/963 (0.10%)	1/471 (0.21%)
Convulsion † 1		
# participants affected / at risk	0/963 (0.00%)	2/471 (0.42%)
Dementia † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Dizziness † 1		

# participants affected / at risk	4/963 (0.42%)	1/471 (0.21%)
Grand mal convulsion † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Headache † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Presyncope † 1		
# participants affected / at risk	3/963 (0.31%)	0/471 (0.00%)
Somnolence † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Subarachnoid haemorrhage † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Syncope † 1		
# participants affected / at risk	2/963 (0.21%)	5/471 (1.06%)
Thalamic infarction † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Transient ischaemic attack † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Unresponsive to stimuli † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Psychiatric disorders		
Abnormal behaviour † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Aggression † 1		
# participants affected / at risk	2/963 (0.21%)	4/471 (0.85%)
Behavioural and psychiatric symptoms of dementia † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Confusional state † 1		
# participants affected / at risk	1/963 (0.10%)	3/471 (0.64%)
Delusion † 1		
# participants affected / at risk	1/963 (0.10%)	1/471 (0.21%)
Depression † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Hallucination † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Insomnia † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Mental status changes † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Paranoia † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Poriomania † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Suicide attempt † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Renal and urinary disorders		
Calculus ureteric † 1		

# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Renal failure † 1		
# participants affected / at risk	0/963 (0.00%)	1/471 (0.21%)
Renal failure acute † 1		
# participants affected / at risk	3/963 (0.31%)	0/471 (0.00%)
Urinary retention † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Reproductive system and breast disorders		
Breast mass † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Dyspnoea † 1		
# participants affected / at risk	2/963 (0.21%)	1/471 (0.21%)
Pneumomediastinum † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)
Pneumonia aspiration † 1		
# participants affected / at risk	3/963 (0.31%)	0/471 (0.00%)
Pulmonary embolism † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	2/963 (0.21%)	0/471 (0.00%)
Hypotension † 1		
# participants affected / at risk	2/963 (0.21%)	1/471 (0.21%)
Orthostatic hypotension † 1		
# participants affected / at risk	1/963 (0.10%)	0/471 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA v11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	All adverse events (AEs) were recorded from the time of informed consent until after the Final Visit or Early Termination.
Additional Description	Serious adverse events (SAEs) were monitored through the termination visit and through 30 days after study drug discontinuation, whichever was longer.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Donepezil SR 23 mg	Donepezil sustained release (SR) 23 mg in combination with placebo corresponding to donepezil IR 10 mg ; dosing

	continued for a 24-week treatment period.
Donepezil IR 10 mg	Donepezil immediate release (IR) 10 mg in combination with placebo corresponding to donepezil SR 23 mg; dosing continued for a 24-week treatment period.

Other Adverse Events

	Donepezil SR 23 mg	Donepezil IR 10 mg
Total, other (not including serious) adverse events		
# participants affected / at risk	**233/963 (24.20%)**	**50/471 (10.62%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**76/963 (7.89%)**	**25/471 (5.31%)**
Nausea † 1		
# participants affected / at risk	**113/963 (11.73%)**	**16/471 (3.40%)**
Vomiting † 1		
# participants affected / at risk	**86/963 (8.93%)**	**12/471 (2.55%)**
Metabolism and nutrition disorders		
Anorexia † 1		
# participants affected / at risk	**51/963 (5.30%)**	**8/471 (1.70%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA v11.1

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: Eisai Inc.
Organization: Eisai Call Center
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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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