

The Video Imaging Synthesis of Treating Alzheimer's disease study

Submission date 01/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/09/2005	Overall study status Completed	☐ Protocol
Last Edited 02/11/2022	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

DCT-49981

Study information

Scientific Title

Evaluating the effects of galantamine HBr using Goal Attainment Scaling (GAS) in a placebo-controlled trial of mild to moderate Alzheimer's disease subjects

Acronym

VISTA

Study objectives

To access the efficiency of galantamine in terms of the goals established by:

1. Patients with AD and their primary carers
2. Treating physicians

Please note that as of 03/03/2009 this record was updated; all updates can be found in the relevant field under the above update date. Please note that the actual trial dates have varied from the anticipated trial dates, the anticipated trial dates at the time of registration were:

Initial anticipated start date: 01/07/2001

Initial anticipated end date: 30/06/2003

At this time, the acronym was changed from 'GAS' to 'VISTA', and the public title was added as above. The original public title has been moved to the scientific title field as this is more appropriate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 03/03/2009: Queen Elizabeth II Health Sciences Centre (now Capital Health) Research Ethics Board (Canada) approved on 9th October 2001

Primary study design

Interventional

Study design

Multi-centre, randomised, double-blind, placebo-controlled trial, followed by an open-label phase

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Alzheimers disease (AD)

Interventions

Added as of 03/03/2009:

Galantamine group:

1. Placebo-controlled phase: galantamine 4 mg twice daily (b.i.d.) for 4 weeks, followed by galantamine 8 mg b.i.d. for 4 weeks (end of week 8), followed by galantamine flexibly dosed at 8 - 12 mg b.i.d. for 8 weeks (end of week 16)
2. Open-label phase: galantamine 8-12 mg b.i.d. for 16 weeks (end of week 32)

Control group:

1. Placebo-controlled phase: placebo matched to galantamine 4, 8 and 12 mg twice daily for 16 weeks

2. Open-label phase: galantamine 4 mg b.i.d. for 4 weeks (end of week 20), followed by galantamine 8 mg b.i.d. for 4 weeks (end of week 24), followed by galantamine flexibly dosed at 8 - 12 mg b.i.d. for 8 weeks (end of week 32)

Initial information at time of registration:

Intervention: Flexible dosed galantamine (16 - 24 mg/day) in mild to moderate AD patients, with 16 week open label follow-up

Control: Placebo

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Galantamine

Primary outcome(s)

Goal Attainment Scaling (GAS) Score at 16 weeks

Key secondary outcome(s)

Measured at 16 weeks:

1. Alzheimer's Disease Assessment Scale Cognitive Subscale (ADAS-Cog)
2. Clinicians' Interview-Based Impression of Change-Plus Caregiver Input (CIBIC-Plus)
3. Disability Assessment for Dementia (DAD)
4. Caregiver Burden Scale (CBS)

The following were exploratory outcomes:

Red Pen Task, Examination of Memory and Temporality, Allocation of Caregiving Time Survey

Completion date

09/03/2005

Eligibility

Key inclusion criteria

1. Written informed consent
2. Aged greater than or equal to 50 years old, either sex
3. Diagnostic evidence of mild to moderate AD consistent with the national institute of neurological communicative disorders and the Alzheimers disease and related disorders association (NINCDS-ADRDA)
4. A history of cognitive decline that has been gradual in onset and progressive over a period of at least 6 months
5. A reliable carer
6. A mini-mental state examination (MMSE) score of 10-25 inclusive at screening
7. An Alzheimers disease assessment scale-cognitive section (ADAS-cog-11) score of at least 18 at screening
8. Sufficient health based upon pre-trial physical/neurological examination

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

130

Key exclusion criteria

1. Other neurodegenerative disorders
2. Other conditions possibly resulting in cognitive impairment
3. Multi-infarct dementia or clinically active cerebrovascular disease
4. Coexisting medical conditions such as epilepsy, psychiatric disease, peptic ulcer, urinary outflow obstruction, or significant hepatic, renal, pulmonary, metabolic or endocrine disturbances
5. Clinically significant cardiovascular disease
6. Any agent used for the treatment of dementia
7. History of drug or alcohol abuse within the last year or prior prolonged history
8. Female subjects who are not surgically sterile or post menopausal
9. History of severe drug allergy or hypersensitivity

Date of first enrolment

29/10/2001

Date of final enrolment

09/03/2005

Locations

Countries of recruitment

Canada

Study participating centre

Divisions of Geriatric Medicine and Neurology

Halifax, Nova Scotia

Canada

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Sponsor information

Organisation

Dalhousie University (Nova Scotia) (Canada)

ROR

<https://ror.org/01e6qks80>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: DCT-49981)

Funder Name

Janssen-Ortho Inc. (Canada) (original)

Funder Name

Janssen-Ortho Inc. (Canada) (supplemental funding)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	:	11/04/2006		Yes	No
Other publications	:	03/04/2007		Yes	No
Other publications	:	01/10/2008		Yes	No
Other publications		31/03/2017	02/11/2022	Yes	No

