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The Video Imaging Synthesis of Treating Alzheimer's disease study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Goal Attainment Scaling (GAS) Score at 16 weeks

Secondary outcome measures
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

Overall study start date
29/10/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
152

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
B3H 2E1

Sponsor information

Organisation
Dalhousie University (Nova Scotia) (Canada)

Sponsor details
1236 Henry Street
Halifax, Nova Scotia
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Sponsor type
University/education

Website
http://www.dal.ca/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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