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Randomised double-blind placebo controlled trial of effect of Ginkgo biloba on cognitive function in mild-moderate dementia

Submission date	Recruitment status	[X] Prospectively registered
02/08/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2007	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

Protocol serial number
QRD/2001/01/07

Study information

Scientific Title

Acronym
DIGGER

Study objectives
Null Hypothesis: high purity ginkgo biloba extract does not improve cognition quality of life or carer burden in individuals with mild-moderate dementia. NB: this study will also assess the magnitude of the Hawthorne effect in dementia trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from Multi-centre Research Ethics Committee (ref: MREC/02/6/35).

Study design
Randomised double-blind placebo controlled parallel group study

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Dementia

Interventions
1. The active intervention will be concentrated, standardised Ginkgo biloba extract (25% active Ginkgo-flavoneglycosides), prepared according to accepted guidelines in a 60 mg tablet (EGB-761, Schwabe)
2. The placebo will be 60 mg of inert lactose with 2 mg quinine sulphate

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ginkgo extract

Primary outcome(s)
Alzheimer's Disease Assessment Scale Cognitive Subscale (ADAS-cog) at six months.

Key secondary outcome(s))
All at six months:
1. Participant: Quality of Life scale in Alzheimers disease (QoL-AD), Neuropsychiatric Inventory

questionnaire (NPI), Geriatric Evaluation by Relative's Rating Instrument (GERRI), adverse events
2. Carer: European Quality of life questionnaire (EQ-5D), Zarit caregiver Burden Interview (ZBI)

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Aged 55 years and over
2. Clinician's diagnosis of dementia
3. Presence of a carer
4. Consent of patient and carer
5. Sufficient command of English to complete questionnaires
6. Mini Mental State Examination (MMSE-23) score of 15 - 24

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Commencement of acetylcholinesterase therapy within two months of recruitment
2. Current anticoagulant therapy
3. Abnormal clotting profile

Date of first enrolment
01/04/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Senior Lecturer
London
United Kingdom
W10 6DZ

Sponsor information

Organisation
Alzheimer's Society (UK)

ROR
https://ror.org/0472gwq90

Funder(s)

Funder type
Charity

Funder Name
Alzheimer's Society (UK)

Alternative Name(s)
alzheimerssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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	Results	03/07/2007		Yes	No