

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

Submission date 02/08/2002	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/07/2007	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Not Specified

Participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/04/2003

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

Age group

Senior

Sex

Both

Target number of participants

Target: 200

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

England

United Kingdom

Study participating centre

Senior Lecturer

London

United Kingdom

W10 6DZ

Sponsor information

Organisation

Alzheimer's Society (UK)

Sponsor details

Gordon House

10 Greencoat Place

London

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SW1P 1PH

+44 (0)20 7306 0606

enquiries@alzheimers.org.uk

Sponsor type

Charity

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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