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Making Evidence-based Decisions Using Alzheimer Therapy (MEDUSA Therapy)

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2016	Nervous System Diseases	[ ] Record updated in last year

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
N0038133699

Study information

Scientific Title
Making Evidence-based Decisions Using Alzheimer Therapy (MEDUSA Therapy)

Study objectives
What evidence is there that altering therapy, after initial treatment starts to fail, will benefit the patient?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Alzheimer's disease

Interventions
Randomised controlled trial (RCT):
1. Cholinesterase inhibitor (ChEi) as usual
2. Increased dose of ChEi
3. Rivastigmine
4. Memantine
5. ChEi as usual, plus memantine

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cholinesterase inhibitor, rivastigmine, memantine

Primary outcome measure
1. Clinical Global Impression of Change (CGI/C)
2. Mini-Mental State Examination (MMSE)
3. BAYER-Activities of Daily Living (ADL)
4. Neuropsychiatric inventory questionnaire (NPI-Q)
5. Global Assessment Scale (GAS)

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/09/2003

Completion date
01/12/2004

Eligibility

Key inclusion criteria
75 participants (i.e. 15 in each arm of the trial) with diagnosis of Alzheimer's disease (AD) and aged between 55 and 95

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
75

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
30/09/2003

Date of final enrolment
01/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Victoria Hospital
Swindon
United Kingdom
SN1 4HZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Avon and Wiltshire Mental Health Partnership NHS Trust (UK)

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