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A randomised, double blind, placebo-controlled clinical trial to compare the progression of cognitive impairment in dementia patients continuing to take, or discontinued from, treatment with neuroleptics

Submission date
30/09/2005

Registration date
30/09/2005

Last Edited
11/11/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof CG Ballard

Contact details
Institute for Ageing and Health
Newcastle General Hospital
West Road
Newcastle upon Tyne
United Kingdom
NE4 6BE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0504126576

Study information

Scientific Title

Study objectives
The hypothesis that the study is designed to test is that in a randomised study, treatment with neuroleptic agents will be associated with an accelerated rate of cognitive decline in dementia patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, double blind, placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
International

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Nervous System Diseases: Dementia

Interventions
Dementia patients continuing to take, or discontinued from, treatment with neuroleptics.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Neuroleptics

Primary outcome measure
The primary outcome will be cognitive change on the Severe Impairment Battery.

Secondary outcome measures
The ADL measures, CAMCOG (including MMSE), FAST and other cognitive assessments will be evaluated as secondary outcomes.

Overall study start date
01/06/2002

Completion date
31/05/2007

Eligibility

Key inclusion criteria
220 patients who will be living in nursing homes, at home with a carer, or in sheltered accommodation who fulfil the NINCDS/ADRDA for probable or possible Alzheimer's Disease and who have been taking neuroleptic medication for a minimum of three months

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
220

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2002

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute for Ageing and Health
Newcastle upon Tyne
United Kingdom
NE4 6BE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Northumbria Healthcare 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2008		Yes	No