

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2005	Overall study status Completed	☐ Protocol
Last Edited 11/11/2008	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised, double blind, placebo-controlled clinical trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Institute for Ageing and Health

Newcastle upon Tyne

United Kingdom

NE4 6BE

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

Northumbria Healthcare NHS Trust (UK)

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	01/04/2008		Yes	No