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Neuroleptics in adults with Aggressive CHallenging Behaviour and Intellectual Disability

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/07/2009	Mental and Behavioural Disorders	

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
HTA 01/07/02

Study information

Scientific Title

Acronym
NACHBID

Study objectives
A multi-centre randomised controlled trial to recruit sufficient learning disability patients to test the null hypotheses that:
1. Compared to placebo antipsychotic drugs do not reduce the incidence of aggressive behaviour in those with learning disability and challenging behaviour.
2. There is no difference between the cost-effectiveness of prescribing risperidone, haloperidol or placebo in those with aggressive challenging behaviour.

More details can be found at: http://www.hta.ac.uk/1322
Protocol can be found at: http://www.hta.ac.uk/protocols/200100070002.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Three-arm double blind parallel placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Mental and behavioural disorders: Schizophrenia and other psychoses

Interventions

A three-arm double blind parallel design trial of placebo, haloperidol and risperidone. Block randomisation utilised with even distribution of each drug in every block, thus no gross disparity. Assessments at baseline, four weeks, twelve weeks and six months. All patients have the option of other treatments as usual during this period with the exception of any other anti-psychotic drugs.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
antipsychotic drugs

Primary outcome measure
1. Multi-axial Classification - multi-axial classification DSM-IV format with ICD10 codes.
2. Mini PAS-ADD - for psychiatric symptoms.
3. Modified Overt Aggression Scale (MOAS) - for aggressive challenging behaviour (ACB). (primary outcome measure)
4. Aberrant Behaviour Checklist (ABC) - Community - for challenging behaviour (ACB). (secondary outcome measure)
5. Client Service Receipt Inventory (CSRI) - Short version for service costs. (secondary outcome measure)
6. Clinical Global Impressions Scale (CGI) - for illness and global improvement.
7. Uplift/Burden Scale - for burden of care of carers.
8. Quality of Life Questionnaire (QOL-Q) - client quality of life.
9. Udvalg for Kliniske Undersogelser (UKU) Side Effect Rating Scale - includes extra-pyramidal side effects.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/08/2002

Completion date
30/11/2007

Eligibility

Key inclusion criteria
Patients who have not taken any depot anti-psychotics in the past three months or oral anti-psychotics in the past week but may have received anti-psychotics in the past.

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
86 patients

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2002

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
Australia

England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W2 1PD

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
South Kensington Campus
London
England
United Kingdom
SW7 2AZ

Sponsor type

University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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	05/01/2008		Yes	No
Results article	results	01/04/2009		Yes	No