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

Contact name

Prof Peter Tyrer

Contact details

Imperial College London Room 4.02 The Paterson Centre 20 South Wharf Road London United Kingdom W2 1PD +44 (0) 20 7886 1648 p.tyrer@imperial.ac.uk

Additional identifiers

Protocol serial number 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

Study type(s)

Not Specified

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(s)

- 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.

Key secondary outcome(s))

Not provided at time of registration.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

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

United Kingdom

England

Australia

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

Sponsor information

Organisation

Imperial College London (UK)

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	05/01/2008		Yes	No

results Results article 01/04/2009

Yes

No