

Anti-psychotic drug reduction in primary care for adults with learning disabilities

Submission date 25/03/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/08/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

About 1 in 200 adults are recognised as having a learning disability. Illness in this population is high, including significant rates of challenging behaviour and mental illness. Use of psychoactive medication is high and there is particular concern over the use of anti-psychotic medication that is prescribed for reasons other than the treatment of psychosis. Control of challenging behaviour is the primary reason why such medications are prescribed despite the absence of good evidence for any therapeutic effect for this purpose. This problem is central to the intervention being evaluated in this study.

Who can participate?

Patients aged 18 and over and their carers from across South Wales and various locations in England from learning disabilities registers

What does the study involve?

Participants are randomly allocated to the intervention group or the control group. Participants meet with the research team five times over the course of 12 months to complete assessments. During the study, those in the intervention group proceed through four monthly approximately 25% reduction stages within a 6-month period (although blinded, the GP has discretion to delay progression to the next step). The control group maintain baseline treatment. Treatment achieved at 6 months is maintained for a further 3 months under blind conditions. At 9 months, the blinding is broken for clinicians and participants and medication changes monitored over the 12-month period.

What are the possible benefits and risks of participating?

Taking part in the study may not necessarily bring about immediate benefits but the information gained will help treat people who will take either Haloperidol or Risperidone in the future. The main risk is that the patient might start to feel worse if their study medication is reduced. GPs receive support in order to know how best to handle any such situations.

Where is the study run from?

The South East Wales Trials Unit at Cardiff University (UK)

When is the study starting and how long is it expected to run for?

April 2013 to June 2016

Who is funding the study?

National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?

Prof. Michael Kerr

KerrMP@Cardiff.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Michael Kerr

Contact details

Psychological Medicine and Neurology

School of Medicine

Cardiff University

Cardiff

United Kingdom

CF14 4YS

+44 (0)29 206 87213

KerrMP@cardiff.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2013-000389-12

Protocol serial number

HTA 10/104/20, SPON 1173-12

Study information

Scientific Title

ANDREA-LD: ANti-psychotic Drug REduction in primary care for Adults with Learning Disabilities (ANDREA-LD): a randomised double-blind placebo-controlled trial

Acronym

ANDREA-LD

Study objectives

To evaluate the impact of a blinded anti-psychotic medication withdrawal programme for adults with learning disabilities (LD) without psychosis compared to treatment as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee for Wales, 04/04/2013, ref: 13/WA/0034

Study design

Randomised double-blind placebo-controlled non-inferiority withdrawal trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Learning disabilities

Interventions

Participants will be taking either risperidone or haloperidol at the start of the study. They will then be randomised to either the dose reduction arm or the treatment as normal arm. Those in the dose reduction arm will have their original (baseline) level of risperidone or haloperidol reduced in 4 (approximately 25%) reduction stages. This is a double blinded study so all study medication will be encapsulated. For those undergoing the reduction, a placebo will also be introduced in order to maintain the number of pills being administered. The control group will maintain baseline treatment. Treatment achieved at 6 months will be maintained for a further 3 months under blind conditions. At this point the blind is broken for the final 3 months of the study in order to monitor prescribing habits.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Risperidone, haloperidol

Primary outcome(s)

Aggression, evaluated using the Modified Overt Aggression Scale (MOAS). The MOAS rates four categories of aggression (verbal aggression, destruction of property, self-mutilation and physical aggression to others) measured at baseline, 6 months, 9 months and 12 months.

Key secondary outcome(s)

1. Adaptive behaviour, measured using the Adaptive Behaviour Scale (ABS) at screening
2. Mental health, measured using the Psychiatric Assessment Schedule for Adults with Developmental Disability Checklist (PAS-ADD) at screening, baseline, 6 months, 9 months and 12 months
3. Adverse effects of psychotropic medication, measured using the Udvalg for Kliniske Undersøgelser scale (UKU) at baseline and 9 months
4. Movement disorders, measured using the Dyskinesia Identification System Condensed User Scale (DISCUS) at baseline and 9 months

5. Other challenging behaviour, measured using the Aberrant Behaviour Checklist (ABC) at baseline, 6 months, 9 months and 12 months

6. Costs, measured using the Client Service Receipt Inventory [modified] (CSRI) at baseline, 6 months, 9 months and 12 months

Completion date

30/06/2016

Eligibility

Key inclusion criteria

1. Aged 18 or over
2. Have a learning disability as judged by administrative classification (e.g. on practice learning disability register, in receipt of an annual learning disability health check, in receipt of learning disability services) and a score on the Adaptive Behaviour Scale that converts to an estimated IQ of 70 or below using the method described by Moss and Hogg
3. Currently prescribed one of two anti-psychotic drugs, haloperidol or risperidone, for treatment of challenging behaviour

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Current diagnosis of psychosis
2. Known recurrence of psychosis following previous drug reduction in the past 3 years
3. The clinician responsible for their treatment judges for any other reason that the participation in a drug reduction programme may be counter-indicated.

Date of first enrolment

01/11/2013

Date of final enrolment

01/02/2015

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Cardiff University

Cardiff

United Kingdom

CF14 4YS

Sponsor information

Organisation

Cardiff University (UK)

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2017		Yes	No
HRA research summary			28/06/2023	No	No