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

Submission date
25/03/2013

Recruitment status
No longer recruiting

Registration date
08/04/2013

Overall study status
Completed

Last Edited
06/08/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2013-000389-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/04/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
310

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)

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Sponsor type
University/education

Website

http://www.cardiff.ac.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, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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