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How does the regular standardized assessment of antipsychotic-induced side effects in forensic psychiatric patients affect the management of these side effects?

Submission date
12/09/2003

Recruitment status
Stopped

Registration date
12/09/2003

Overall study status
Stopped

Last Edited
22/08/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Albert Ngan

Contact details
Pharmacy Department
Homerton University Hospital NHS Trust
Homerton Row
London
United Kingdom
E9 6SR
+44 020 8510 7252
albert.ngan@homerton.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0024108481

Study information

Scientific Title

Study objectives
To identify the effect of the introduction of two assessment scales to regularly appraise antipsychotic-induced side effects in forensic psychiatric patients on management of these side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised 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: Psychosis

Interventions
1. Self-rating Anxiety Scale (SAS) & Brief Agitation Rating Scale (BARS) assessment + ongoing reassessments
2. Standard care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Changes/differences in the SAS and BARS rating at the baseline and the end-assessment within the control and the study group and between the groups. Differences in the general mental health rating at the beginning and the end-assessment between the control and the study groups. Association between SAS + BARS assessment and the general mental health status.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2003

Completion date
31/10/2003

Reason abandoned (if study stopped)
Lack of staff

Eligibility

Key inclusion criteria
30 + 30 patients, Forensic Mental Health Unit.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2003

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Pharmacy Department
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Homerton University Hospital NHS Trust (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