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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Pharmacy Department
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Homerton University Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration