

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 22/08/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Primary study design

Interventional

Study design

Randomised controlled trial

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