Optimising individualised prescribing with therapeutic drug Monitoring for Antipsychotics (OptIMA) 2: clinical pilot study of antipsychotic drug level monitoring

Submission date 10/09/2010	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 04/11/2010	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 07/08/2020	Condition category Mental and Behavioural Disorders	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Maxine Patel

Contact details Institute of Psychiatry, King's College London Box 68 16 De Crespigny Park London United Kingdom SE5 8AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Optimising Individualised prescribing with therapeutic drug Monitoring for Antipsychotics (OptIMA) 2: Clinical pilot study of antipsychotic drug level monitoring - a pilot multicentre openlabel single-arm clinical trial

Acronym

OptIMA 2

Study objectives

The aim is to refine the method of using plasma level therapeutic drug monitoring (TDM) for olanzapine/risperidone for individual patient antipsychotic dose management in routine acute inpatient settings. This will include confirmation of logistics, methods and refinement of guidance on interpretation of the plasma level results. This includes method for sending samples from various hospital sites to the laboratory, laboratory assay request forms for study participants, clinician understanding and use of algorithm, and speed of rapid feedback of online TDM results to clinicians.

This will be a pilot clinical trial study which is small scale in design for 30 inpatients with acute psychosis prescribed olanzapine or risperidone, with 6-week follow-up data capture. The intervention is assessment of antipsychotic blood levels (plasma concentrations) and this will be conducted for all participants.

This is the second of three studies in the project entitled 'Optimising Individualised prescribing with therapeutic drug Monitoring for Antipsychotics (OptIMA)'.

Ethics approval required

Old ethics approval format

Ethics approval(s) South East Research Ethics Committee (REC), ref: 10/H1102/59

Study design

Small-scale multicentre open pilot clinical trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Schizophrenia, schizoaffective disorder

Interventions

Medication decisions will be made by the participant's own clinician.

The intervention is TDM with rapid results feedback and a clinician guidance algorithm. A plasma level blood sample, 12 hours post-dose, will be collected 7 - 14 days after drug initiation. The sample will be sent with a trial-specific lab analysis request form to the laboratory. The lab results will be available via a secure online system within a target of 3 working days.

The drug concentration method of analysis at this lab will be high performance liquid chromatography with mass spectrometry. The assay is fully validated to FDA GLP standards. Sample requirement is 2 ml plasma (4 ml whole blood required).

Repeat TDM with feedback will be allowed (up to two further times) until a drug plasma level in the olanzapine 20 - 40 ng/mL target range (or risperidone 20 - 60 ng/mL) is reached or up to the point of discharge from the inpatient unit, whichever is earlier.

The newly created clinician guidance algorithm will enable the participant's clinicians to optimise prescribing for individuals based on an objective measure and will facilitate lowest effective dose prescribing. It will also enable clinicians to identify patients with drug levels above the therapeutic window who are at risk of toxicity. It will inform prescribing with plasma levels not as the sole determinant of dosage, but importantly in conjunction with the clinician's and patient s assessment of symptom change, side effects, and medication adherence.

Participant decision optional extra:

A saliva test for olanzapine or risperidone saliva levels will be offered to the participant. This will be at same time as the primary intervention and will be in addition to the blood test (and not instead of the blood test). The purpose for doing this extra saliva test is to seek evidence of equivalence in accuracy between blood samples and saliva samples for antipsychotic drug level measurements. Although saliva sample testing technology exists, its accuracy and equivalence has not yet been confirmed in comparison to blood sample testing.

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

- 1. Total daily prescribed dose, measured at 6 weeks follow-up
- 2. Drug discontinuation, measured at 6 weeks follow-up

Outcome measures will be based on a review of case notes and further participant direct contact will not be required.

Secondary outcome measures

Measured at 6 weeks follow-up:

1. Documented evidence of clinician checking the test results, changes to medication regimen (including dose titration)

2. Duration of in-patient stay (and also days in psychiatric intensive care)

3. Use of short-acting intramuscular medication (benzodiazepines, etc.)

4. Rehospitalisation

5. Legal detention status

6. Accuracy and equivalence of saliva antipsychotic level testing in comparison to blood sample testing

Overall study start date

01/10/2010

Completion date

30/09/2011

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years, either sex

2. Schizophrenia/schizoaffective disorder (clinician International Classification of Disease [ICD-10] diagnosis)

3. Symptoms of acute psychosis

4. Admitted in past two weeks to participating inpatient acute wards

5. Routine clinician initiation (including switch/new initiation/recommencement) of regularly daily prescribed olanzapine as antipsychotic monotherapy, i.e., only one daily antipsychotic drug 6. Legally detained participants will be permitted if they have capacity to consent to the study

Participant type(s)

Patient

Age group

Adult

Lower age limit 18 Years

Sex

Both

Target number of participants Recruitment of 30 patients

Total final enrolment

Key exclusion criteria

1. Use of clozapine in past 12 months (i.e. whose illness has been classified as 'treatment resistant') but who are now prescribed olanzapine. This is because they would not be expected

to benefit from changes in olanzapine dosage.

2. Use of another simultaneous regularly prescribed daily antipsychotic (other than p.r.n) at study onset

Date of first enrolment 01/10/2010

Date of final enrolment 30/09/2011

Locations

Countries of recruitment England

United Kingdom

Study participating centre Institute of Psychiatry, King's College London London United Kingdom SE5 8AF

Sponsor information

Organisation Institute of Psychiatry, Kings College London (UK)

Sponsor details c/o Ms Jennifer Liebscher 16 De Crespigny Park London England United Kingdom SE5 8AF

Sponsor type University/education

Website http://www.iop.kcl.ac.uk/

ROR https://ror.org/0220mzb33

Funder(s)

Funder type Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Clinician Scientist Fellowship Award (ref: NIHR/CS/009/010)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015	07/08/2020	Yes	No