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Optimising Individualised prescribing with therapeutic drug Monitoring for Antipsychotics (OptIMA)3: clinical pilot study of antipsychotic drug level monitoring for dose review

Submission date
14/10/2014

Recruitment status
Stopped

Registration date
12/11/2014

Overall study status
Stopped

Last Edited
07/10/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Antipsychotics are the main medication of choice for treating mental illnesses such as psychosis and schizophrenia. How these medications are prescribed has remained relatively unchanged for over 50 years. Decisions regarding how much patients should take (the dose) are made without tests or objective clinical measures. Quite often, patients are prescribed the maximum licenced dose of their medication, and in some cases, even more. Monitoring the amount of medicine in the blood may help in decision-making regarding the amount of the drug that should be given, by helping to ensure that there is the right amount of medication, not too much or too little, for the individual person. This is because there is much variation in how different peoples bodies react to different doses. For example, smoking can affect how the human body reacts to drugs. The aim of this study is to investigate the use of drug levels in the blood for antipsychotics, otherwise known as therapeutic drug monitoring (TDM). This will help to improve the techniques currently available and to work out which methods are acceptable to both patients and clinicians (such as doctors).

Who can participate?
Patients aged 18-65 years from inpatient wards or outpatient clinical services, who are regularly prescribed olanzapine or risperidone (two types of antipsychotic drugs)

What does the study involve?
Participants have a clinical interview with a member of the research team. This includes questions about their current mental and physical health and their prescribed medication. A blood sample is taken up to a few days after the interview. The amount of antipsychotic drug in their blood is measured and the test w made available to their doctor. The doctor may then decide whether or not the dose should be adjusted (increased or reduced). If the dose is adjusted, further blood tests may be suggested in order to check that the adjusted dose has in fact changed the level of the drug in the participants blood. Between four and eight weeks later, there is another clinical interview and final blood sample taken.

What are the possible benefits and risks of participating?
As regards to benefits, there is a potential that the blood test results may help psychiatrists to better understand how an individuals body is coping with the antipsychotic medication. This may then be used, in addition to other factors such as the severity of the illness, to allow for prescribing drugs tailored to each individual patient. The potential risks and/or disadvantages of participating include answering questions in the clinical interviews that may be sensitive or upsetting, some possible short-lasting discomfort and bruising from the blood test, and a possible delay in taking morning medication until after the research blood sample has been taken.

Where is the study run from?
The study was set up at the Institute of Psychiatry, King's College London and is being run in the following NHS trusts: South London and Maudsley NHS foundation trust; Central and North West London NHS foundation trust; West London Mental Health NHS trust; South West London and St Georges Mental Health NHS trust; North Essex Partnership NHS foundation trust; and Barnet, Enfield and Haringey NHS trust.

When is the study starting and how long is it expected to run for?
December 2014 to May 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Maxine Patel

Contact information

Type(s)
Scientific

Contact name
Dr Maxine Patel

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Additional identifiers

Study information

Scientific Title
Optimising Individualised prescribing with therapeutic drug Monitoring for Antipsychotics (OptIMA) 3: clinical pilot study of antipsychotic drug level monitoring for dose review - a pilot multicentre open-label single-arm clinical trial

Acronym
OptIMA 3

Study objectives
It is hypothesised that the level of risperidone/olanzapine in participant's blood (plasma drug levels)will be within the therapeutic range 4-8 weeks after a first blood sample has been taken for therapeutic drug monitoring.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Small-scale multicentre open pilot clinical trial (nonCTIMP)

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychotic disorders

Interventions
The intervention is Therapeutic Drug Monitoring with rapid results feedback and a clinician guidance algorithm.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Risperidone, olanzapine

Primary outcome(s)
The proportion of participants whose drug plasma level is within target therapeutic range at follow-up (between 4 and 8 weeks after participation in the trial)

Key secondary outcome(s))
The proportion of participants whose plasma drug level, at follow-up (between 4 and 8 weeks after participation in the trial), falls within the range above or below the target therapeutic range. The acceptability of these suboptimal plasma level ranges will be assessed with regards to tolerance and clinical response. Tolerance will be measured using the side effect rating scales and response using the Positive and Negative Syndrome Scale at follow-up.

Completion date
31/05/2015

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. People admitted to participating inpatient wards or those under the care of an outpatient clinical service
2. People for whom the treating clinician has identified a need for antipsychotic dose review within routine clinical care
3. Age 18-65 years
4. Current diagnosis from one of the diagnostic categories of ICD-10: F20-F29
5. Regularly prescribed oral olanzapine or risperidone as monotherapy for the treatment of psychotic symptoms
6. Legally detained participants will be included if they have capacity to consent to the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Current diagnosis of drug induced psychosis (ICD-10 F10-19)
2. Use of clozapine in past 12 months

Date of first enrolment
01/12/2014

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Clinician Scientist Fellowship Award

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration