South East Wales Trials Unit (SEWTU)
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Study Title:

ANDREA-LD

ANti-psychotic **D**rug **RE**duction in primary care for **A**dults with **L**earning **D**isabilities (ANDREA-LD): A Randomised double-blind Placebo Controlled Study

Information Sheet

Version 2.0

Sponsor: Cardiff University
Study Number: SPON 1173-12

Introduction

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Please take time to decide whether or not you wish to take part and talk to others about the study if you wish. All research is voluntary; you do not have to take part. If you do take part, you can withdraw at any time. This will not affect your medical care in anyway.
(Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study).

PART 1

What is the purpose of the study?
This research study is looking to see if the dose of one particular medication that you are on (either Haloperidol or Risperidone) can be cut without making you feel any worse.

Who is involved?
About 310 people from around Wales and parts of England will take part in this study.

Why have I been invited?
This is because you have been prescribed either Haloperidol or Risperidone and your GP practice has agreed to take part in this study.

Do I have to take part?
No, it is entirely up to you to decide. If you decide to take part you will still be free to withdraw at any time, without giving a reason. Whether you decide to take part or not, or withdraw from the study, your medical care will not be affected in any way.

What will happen to me if I decide I would like to take part?
You and your carer (or representative) will meet with the research team 5 times over the course of 12 months to complete some questionnaires. You will be assigned to one of two groups and either your medication will be reduced or you will take the amount you normally do. You will also visit your GP approximately 4 times so that he or she can make sure you are ok. You will also need to pick up a specific prescription to take.

What will I have to do?
Firstly, one of the research team will meet with you and ask some questions to see if you are eligible ('screening'). Information collected at 'screening' will include the following: age, gender, current medication and psychiatric history. Your doctor will also be asked if he or she is happy for you to take part. The research team will also talk through the study with you to make sure you fully understand what is involved in taking part and are happy to do so – this is called informed consent. If you are happy to participate we will ask you to sign a consent form. The meeting will take place either at your doctor's surgery or at place that is convenient

If you are eligible to take part, the research team will contact you again roughly 1 or 2 months later to arrange another meeting (called the 'baseline' meeting). At this next meeting both you and your carer (or representative who knows you well) will be asked to complete some questionnaires/assessments which ask about your behaviour and whether or not you can do certain things. These should take approximately $1^{1/2}$ to 2 hours and we will need to ask permission from your carer or representative to do this as well. At this meeting you will be randomly allocated into one of two groups.

Each group will receive a different treatment – either you will keep taking your medication

(Haloperidol or Risperidone) as your doctor prescribed or your medication will be gradually reduced. This random allocation is like tossing a coin, you will have a fifty-fifty chance of going into either group. At the end of the study the two groups will be compared to see if one treatment is better than the other.

Will I know which group I am in?
Neither you nor your GP will know which group you are in (although, if there is an emergency, your doctor can find out which treatment group you are in).

What is involved in taking part?
After you have been allocated to a group. you will have to visit your GP on 4 occasions (about once a month) so that they can see how you are doing and give you your study medication.

You (and your carer or representative) will then meet the research team 3 more times. This will be approximately 6, 9 and 12 months after the 'baseline' meeting. Again, you will both be asked to complete some questionnaires.

You will not be asked to give any blood or have any medical or genetics tests.

After the third meeting with the research team (9 months), we would also like to contact your doctor and your carer or Legal or Professional Representative on the phone to discuss what the study was like for them – we will explain this to them in more detail nearer the time.

Finding out which group you were in
After being on the study drug for 9 months, you and your GP will be told which group you were in and it will be up to your doctor to carry on prescribing any medication. You will stop being in the study after 12 months.

Expenses and payments
We are not able to offer payment for taking part in this study.

What will I have to do?
If you decide to take part, it is important that you attend all scheduled visits. It is also important that you take the study drug as directed being sure not to miss any tablets and take the study drug at about the same time each day.

Because of possible interactions with other drugs, you must tell your doctor before taking any other drugs. This includes some prescriptions drugs, over-the-counter medicines, herbal medications and vitamins.

If you have private health insurance you should tell your insurers that you are taking part in a clinical trial.

Is it a new drug that is being tested?
No, the study is looking at reducing Riperidone and Haloperidol, which are often used to try and help make people feel calmer if they have felt aggressive and agitated.

What are the possible disadvantages and risks of taking part?
It is possible that you might start to feel worse when you take part in the study. You might also have to attend more appointments at your GP surgery than you normally do and do some questionnaires.

What are the side effects of any treatment received when taking part?
Along with their useful effects all medicines can cause unwanted side effects. As you are already taking either Risperidone or Haloperidol, your doctor will have already described any side effects.

If you experience severe side effects, you must tell a doctor immediately so that they can advise you what to do next. All symptoms need to be reported to your doctor or the study team either by phone or at the next study visit.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get will help treat people who will take either Haloperidol or Risperidone in the future.

What happens when the research study stops?
When everyone has finished thestudy, we will analyse the data and prepare and publish a report describing what we found. You will not be identified in any reports or publications resulting from this study.

If the information in Part 1 interests you and you are interested in taking part, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?
If we get new information about the treatment being used, your study doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your study doctor will make arrangements for your standard care to continue. If you decide to continue in the study your study doctor may ask you to sign an updated consent form.

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study or discontinue the study drug at any time without giving any reason and without your medical care or legal rights being affected. If you choose to leave the study or plan to stop taking your study medication, you must speak to your GP first. You will be asked to attend a final study visit for your safety.

What if there is a problem?
If you are not happy with the general care and treatment you receive during the study, please speak first to your study doctor or nurse, who will try to resolve the problem. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your GP or the research team.

What if something goes wrong?
If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

Will my taking part in this study be kept confidential?
If you consent to take part in the research we may look at your medical records to help with analysing the results. Cardiff University and the regulatory authorities (known as the MHRA) may also need to authorise people to look at your records to make sure that the study is being carried out correctly. Your name, however, will not be disclosed outside of the study hospital, except to inform your GP and hospital consultants (if you have any) that you are participating in the study. You will be given a participant identification number (PID), which will be used as a code to identify you on all study forms. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised.

You must also agree that, during the study, you may not have access to some of your medical information obtained or created as part of this study. You will be allowed to access this information once the study is finished. If you withdraw consent from further study treatment, unless you object, your data will remain on file and will be included in the final study analysis.

In line with the regulations, at the end of the study your data will be securely archived for 15 years. Arrangements for confidential destruction will then be made.

Involvement of your General Practitioner (GP) / Family Doctor and Hospital Doctors

Should you agree to participate in this research study your GP will be asked if they are happy for you to take part. Your GP will also inform any hospital doctors (if you have any) of your involvement in the research.

Who is organising and funding the research?
Experts working with Cardiff University have developed this research which will be undertaken in conjunction with the South East Wales Trials Unit. The research is funded by the Health Technology Assessment (HTA) Programme.

Who has reviewed the study?
This study was reviewed by medical and research experts. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee for Wales. In addition this study has been reviewed and approved by the MHRA (Medicines and Healthcare Products Regulatory Authority).

Further information and contact details
If you have questions about this study, please contact:

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Or

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If you do not feel comfortable in speaking with your study doctor, you may contact the Independent Complaints Advocacy Service (ICAS). Details can be obtained from NHS Direct on 0845 4647.