Participant Information Sheet

Using ketamine to prevent relapse of severe depression in people who have had electroconvulsive therapy

The KEEP-WELL Study

“Ketamine for depression relapse prevention following ECT: a randomised pilot trial with blood biomarker evaluation”

Study Site: St Patrick's University Hospital, St James’ St, Dublin 8 and Trinity College Dublin

Principal Investigator: Professor Declan McLoughlin

Telephone: 01 2493385

Email: d.mcloughlin@tcd.ie

You are being invited to take part in a study. Before you decide, it is important for you to understand why the study is being done and what it will involve. This Participant Information Sheet will tell you about the purpose, risks and benefits of this study. If you agree to take part, we will ask you to sign a Consent Form. If there is anything you are unclear about, we are happy to explain it to you. Please take as much time as you need to read this. You should only consent to take part in this study when you feel that you understand what is being asked of you, and you have had enough time to make your decision. Thank you for reading this.

Purpose of the Study

Depression is a major public health problem in Ireland. Electroconvulsive therapy (ECT) is a safe, effective treatment for severe depression. About 500 people have this treatment per year in Ireland. We would like to study the biology of depression by comparing proteins in the blood, called “biomarkers”, between people who have severe depression and are having ECT, and people who are healthy. We will look at some specific messenger chemicals involved in depression, and other chemicals that help maintain healthy genes, to see if these are changed by depression and treatment. This is important because we do not yet know exactly how ECT treats depression.

Unfortunately some people, who recover from depression by having ECT, quickly become unwell again, even while taking antidepressants. There is an urgent need to find better treatments to prevent relapse. One possibility is the commonly used anaesthetic drug ketamine. Unlike other antidepressants which may take weeks to have effect, ketamine has been shown to
have a strong, rapid antidepressant effect at low doses. This study is part of a wider study in which we will examine whether repeated low doses of the commonly used anaesthetic drug, ketamine are better than a placebo drug at preventing relapse of depression after ECT.

Why have I been chosen?

You have been asked to participate as a healthy volunteer, i.e. you are not suffering from depression. It is important to have a "control group" of healthy people so we can compare the test results of people who have depression, with results of people who do not have depression.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this Information Sheet to keep and a copy of your Consent Form. If you decide to take part, you can withdraw at any time without giving a reason. A decision to withdraw or not take part will not affect your rights or treatment in any way.

What will happen if I decide to take part?

If you decide to take part as a healthy volunteer in our control group, you will be asked to complete two interviews with a trained researcher and blood tests on two occasions. Part of the interviews will involve mental health questionnaires and memory tests. The blood samples will be used to compare the levels of certain proteins in people who are depressed vs. those who are not depressed.

Other people who take part in this study may be having treatment for depression at the moment, and we will be performing the same tests and interviews with them, with some extra measures. We would be happy to tell you more about this if you would like.

We will make every effort to minimise any inconvenience to you and to run the study to high scientific standards. The blood samples you give will be examined by research scientists at our laboratory in Trinity College Dublin. These staff will only know the identity of your blood sample by a code number and the key to this code and any personal information will be kept confidentially by Professor Declan McLoughlin at St. Patrick's Hospital, Dublin.

How long will my part in the study last?

The study will take four hours of your time in total. This will be in the form of two two-hour interviews four weeks apart. You can withdraw from the study at any time.

What do I have to do?

There are no specific recommendations for taking part in this study as a healthy volunteer, apart from scheduling two interview sessions with you.

What are the possible benefits of taking part?

Taking part in the study will not benefit you directly, but everyone who decides to participate will contribute to scientific knowledge about depression. Some people may benefit from learning more about their memory or mental health during the interviews. The individual results of the tests for biomarkers will not be available to you, and we will not be performing
genetic screening in this study. We can send you a copy of the six-monthly newsletter about the progress of the study if you would like.

**What are the possible disadvantages or risks of taking part?**

The study includes a questionnaire about your mental health and memory. You could find you would like to talk to someone about any issues it raises, we would be happy to recommend someone to you. Other possible risks are those associated with having a blood sample taken. This is a routine and safe procedure and you will probably already have experience of blood tests. Occasionally, minor bruising around the site from which the blood was drawn may occur, but this will quickly disappear. Very rarely, the site may become infected, but this is easily treated. A possible disadvantage to you is the time it takes to be interviewed, completing questionnaires and assessments. To minimise any discomfort, multiple breaks can be taken.

You will receive a phone number so you can always get in touch with one of our researchers if you have any concerns.

**What happens at the end of the study?**

The results of the study will be presented at conferences and published in scientific journals. The identity of people who have taken part will always be kept confidential. Your confidential information will be stored securely for at least five years and will be destroyed after no more than ten years in accordance with the data protection legislation at the time.

Thank you for reading this information sheet.

If you are interested in taking part, please contact:

Prof. Declan McLoughlin

Dept of Psychiatry, Trinity College Dublin,

St Patrick's University Hospital

01 2493385

d.mcloughlin@tcd.ie