Patient Information Sheet (Study Screening)

Methylphenidate versus placebo for fatigue in advanced cancer (MePFAC)

We think that you may be suitable to take part in a research study which will compare a medicine to treat fatigue (methylphenidate) with a dummy pill (placebo). However, before we can make a decision about whether or not you would be suitable for the study we need to ask you some questions about your health, look through your medical records, take some blood tests and check your blood pressure and pulse. This process is known as "screening".

If you think that you may be interested in taking part in the main study then we will first need your permission to be screened. If you do not want to be involved in the trial then there is no point in being screened.

Before you decide whether to be screened for this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

What will the main study involve?

The main study will compare a medication that may help cancer-related fatigue (methylphenidate) with a "dummy pill" (a placebo). Methylphenidate is currently used to treat children with Attention Deficit Hyperactivity Disorder (ADHD), in whom it has been shown to be a safe and effective medication. There is some reason to believe that it may also help adults with cancer-related fatigue, but it has not yet been adequately investigated for this purpose.

If you are involved in the main study you will be given either methylphenidate tablets or placebo for nine weeks. Which treatment you receive will be decided at random using a computer and neither yourself nor your doctors will know which treatment you are receiving. This is to make sure that the study is a "fair test". During the nine week study period you will be in contact with the research team on a weekly basis, either by telephone or at face-to-face meetings. The study will end after nine weeks. At that time, if you are still feeling fatigued, you will be able to discuss with your doctor whether any further treatment is advisable. This may or may not include use of methylphenidate depending upon your individual circumstances at that time.

Full details about the main study are available in the Patient Information Sheet (Study enrolment) version 2 dated 26-Jun-2017.

Why have I been invited to be screened for this study?

Your doctor thinks that you may be suitable to take part in the main study, but before we can make a decision about this we need to carry out some more checks.

Do I have to take part in screening?

No, it is up to you to decide whether or not you take part in the screening. You do not have to take part unless you feel completely happy with what you are being asked to do. If you agree to be screened, we will ask you to sign a consent form and you will be given a copy. You are free to change your mind at any time without giving a reason. Whether or not you decide to be screened will not affect the standard of care you receive.

Even if you agree to take part in screening you are under no obligation to take part in the main study. However, if you know now that you definitely would not want to take part in the main study then there is no point in agreeing to be screened.

What will happen to me if I take part in the screening?

If you agree to take part in screening you will be asked some questions about your health, and will be asked to allow researchers to look through your medical records. If you have not already recently had a blood test which includes the relevant results, then you will need to provide a new 15mls blood sample so that we can check whether your kidney and liver function and blood count are good enough to take part in the main study. You will also have your blood pressure and pulse measured. The whole process should take about 20-30 minutes.

Are there any disadvantages in taking part?

Taking part in screening will take 20-30minutes of your time, and at the end of it, you may not be found suitable to take part in the main study and so you may feel that this has been a waste of your time. There may also be some slight discomfort associated with having a blood test.

What are the possible benefits of taking part?

There are no direct benefits to taking part in screening. However, if you are found to be suitable, then you will be invited to participate in the main study.

Will my GP be informed of my involvement?

We will not inform your GP about the screening unless you are found suitable to take part in the main study and agree to do so.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the study will be kept strictly confidential and in accordance with the Data Protection Act 1998. The blood results, blood pressure and pulse readings will be included in your medical record and shared with your health professionals and with the research team.

So that we can keep in contact with you during the study it will also be necessary to share your personal details (name, address, date of birth, telephone number, medical history) with members of the research team. This is so that we can contact you to let you know the results of the screening tests and to invite you to participate in the main trial if you are found to be suitable.

What happens after screening?

You will be contacted by a member of the research team a few days after the screening to let you know whether or not you are suitable to take part in the main study. If you are not suitable then no further involvement in the research will be required and if you have any further queries about your health or the treatment of your symptoms then these should be directed to your medical team. If you are found to be eligible to take part in the study then you will be invited back to the hospital/hospice for a further visit to discuss the study in more detail and to start the study treatment if you are agreeable.

Who is organising and funding the research?

The study is being organised by the Marie Curie Palliative Care Research Department, Division of Psychiatry, University College London. Funding is from the National Institute for Health Research (NIHR) Health Technology Assessment. Some staff working on the project are supported by Marie Curie funding and infrastructure support.

Who has reviewed this study?

This study has been reviewed and approved for its scientific methods by independent researchers in the field appointed by the research funder.

In addition, all research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by London - City & East Research Ethics Committee (REC reference 17/LO/0871).

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions - please see details below.

If you remain unhappy and wish to complain formally, you can do this through your local Clinical Commissioning Group (CCG) Complaints Procedure. Details can be obtained from the relevant CCG. A member of the research team can help you to get these.

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) negligence then you may be able to claim compensation.

After discussing this with a member of the research team, please make the claim in writing to Professor Patrick Stone who is the Chief Investigator for the clinical trial and is based at the Marie Curie Palliative Care Research Department, Division of Psychiatry, University College London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Participants may also be able to claim compensation for injury caused by participation in this clinical trial without the need to prove negligence on the part of University College London or another party. You should discuss this possibility with a member of the research team (details given at the end of this letter) in the same way as above.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the clinical trial, the normal National Health Service complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this. Details can also be obtained from the Department of Health website: http://www.dh.gov.uk.

What if I have any questions or concerns about the study?

We are providing contact details and telephone numbers and email addresses so you can contact us if you have any questions at any point. We will be happy to ring you back if you wish.

Thank you for taking the time to read this.

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