Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Norfolk & Norwich Skin Tumour Unit

East Anglian Regional Service

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PATIENT INFORMATION SHEET FOR 'MEL-FO' RESEARCH PROJECT

Prospective Randomised Trial for the Evaluation of a Theoretical Follow-up Schedule in Cutaneous Melanoma Patients: The "MEL-FO" Study

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. There will be ample opportunity to clarify any questions or queries you may have throughout this process. You will be given enough time to decide whether or not you wish to take part.

The reason you have been asked to volunteer for this research study is because you have a type of melanoma that we would like to investigate.

Thank you for taking the time to read the information below.

What are we trying to achieve with this study?

Melanoma can be an unpredictable condition and this sometimes makes it difficult for you to know how to view the future. The major concern with melanoma is that, on occasion, it can spread to other parts of the body and when this happens it is called a 'recurrence'. Patients diagnosed with invasive melanoma are followed up in the outpatients clinic on a regular basis and this is designed to detect those people with recurrences of their melanoma promptly. Internationally, there is no agreement of how frequently we should follow-up patients with melanoma. Interestingly, in many instances it is the patients themselves who detect the recurrent melanoma, rather than the doctor in clinic. Furthermore, many patients say that they feel very anxious and worried every time they go to see their doctor in outpatients.

This research will focus of the follow-up of melanoma patients. The aim of the study is to investigate whether less frequent hospital check-ups than the conventional currently recommended schedule improve the quality of life of melanoma patients and their satisfaction with the follow-up schedule. We will also investigate whether the two schedules are equally effective to detect recurrence and/or a second primary melanoma.

What might be the benefits to patients once this study has been completed?

Some participants may be curious to know why seeing the doctor less frequently for follow-up of their melanoma may be of benefit to them. If the theory of this study is shown to be correct then a less frequent follow-up schedule may actually reduce patient anxiety, help patients regain a sense of self-determination and help to improve the quality of care in the outpatients department.

1. ***Reduce patient anxiety***

   Most patients feel extremely anxious when they come to the hospital for their routine outpatient appointment. Understandably, they are worried that the doctor will find something and tell them that their cancer has spread. However, it has been shown from several studies that in the majority of cases, it's actually the patients themselves who find the disease recurrence in-between scheduled outpatient visits. Therefore, if the number of visits is reduced, patients anxiety about follow-up will be reduced and those patients who do find something can be reassured that they can see a doctor rapidly with the minimum of difficulty.

2. ***Regain a sense of self-determination***

   Many patients feel that, when they have been diagnosed with melanoma, they are no longer in complete control of their lives. The fear of a recurrence or a new melanoma occurring and general uncertainty about the future is the main reason patients feel that way. It has been shown for many patients with cancer that they tend to feel that they are regaining that sense of control or self-determination when they are actively involved in their treatment and have been given the information to empower them to do so. In the case of this study, it is expected that patients who have been shown what to look for will catch any new melanoma early at a curable stage.

3. ***Improve the quality of care in outpatients departments***

   It is expected that reorganising the way melanoma patients are followed up will make rapid access to a melanoma clinic when patients have concerns much more efficient. Furthermore, it is expected that this new follow-up schedule will free up valuable time for the doctor to spend with patients who have been newly diagnosed with a melanoma or who have developed further problems with their melanoma. Many doctors and specialists nurses feel that the lack of time available for the patients who most need it is one of the major challenges they face in producing an excellent service for melanoma patients.

How many people will take part in this study?

We aim to study 178 patients. This is an international study and other research sites include the Netherlands and Australia, which will recruit similar numbers.

Do I have to take part in the study?

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 be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Will I definitely have less frequent follow-up appointments?

No. If you enrol in the study, a computer will be used to randomly allocate you to one of the following two groups:

- Conventional schedule; or
- Less frequent schedule

This means that you must be prepared to accept either schedule before you agree, so that you will not be disappointed later.

What does it mean for you to take part in the study?

Your follow-up visits will be identical in both schedules, except for the fact that the number of hospital check-ups will be less frequent in the new proposed schedule. You will play an important role in the examination of your own body, irrespective of the follow-up schedule. Currently, we provide extensive information about melanoma in the form of booklets and leaflets that contain instructions about how examination yourself and this will not change as part of your ongoing care for you regardless of which part of the study you follow. If you have any questions or concerns between your follow-up visits, you will be able to make an appointment to see on of your medical team at any time.

You will be given clear instructions on how to contact the hospital if you notice anything that is of worry to you. This will enable you to access a clinic to see one of the melanoma team specialists to address any concerns about a recurrence or a new primary rapidly and efficiently. If you choose to go to your GP first to discuss any potential recurrence or new melanoma, they will be able to contact us on your behalf to get access to the melanoma clinic too. Regardless of which part of the study you end up on, you will be able to contact one of the clinical nurse specialists as usual to discuss any other concerns about the melanoma you may have. Common questions that the clinical nurse specialist can help you with that patients tend to ask include how to obtain counselling, access to a support group, financial aid and spiritual support.

How long is the study?

The duration of the study is five years. As a participant in the study you will be asked to fill in a questionnaire at various different times. These include, directly after diagnosis and at 6, 12, 24, 36, 48 and 60 months after surgical treatment of the melanoma. These questionnaires will ask you about your mental and physical well-being. The questionnaires will take about 15-20 minutes.

Are there any benefits to taking part in the study?

If you agree to take part in this study, there will not be any direct medical benefit to you. We hope the information learned from this study will benefit other patients with melanoma in the future (see above).

Will I be paid to participate in this study?

You will not be paid for your participation in this study.

What if new information becomes available?

Sometimes during the course of a research project new information becomes available regarding the treatment and follow-up of melanoma patients. If this is likely to affect you, your research doctor will tell you about it and discuss with you whether you want to continue in the study.

If you decide to withdraw, your research doctor will make arrangements for your care to continue. Whilst you are participating in the study, if new information comes to light your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

What if something goes wrong?

If you are harmed by taking part in this research project, 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. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service (NHS) complaints mechanisms should be available to you. If you believe that you have experienced a research-related illness or injury, you must contact Mr Marc Moncrieff immediately (contact details below).

What if I don't what to take part in this study?

Participation in this study is purely voluntary. You are completely free to decide whether or not to take part. If you do participate, you can change your mind at any time and withdraw from the study. You choice will not have any influence on your further treatment and you will continue to receive the current optimal treatment. Your relationship with your medical specialist will not be affected. If you decide to discontinue your participation in this scientific study, you can communicate this at any time verbally or in writing to your medical specialist or the researchers. The information obtained during the follow-up visits in this study will be added to your medical file.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice, and all information about you will be handled in confidence. We will keep your information in confidence. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons involved with the Mel-Fo study. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised. We may use direct quotes that you provide, however, these too will be completely anonymised.

Will my GP be informed of my involvement in the study?

If you agree, we will inform your GP of your involvement in this study.

What will happen to the results of the research study?

The information in this study may be published in medical journals or presented at professional meetings; at no time will it be possible to identify you as a participant of the study.

Who had reviewed this study?

The Cambridgeshire 3 Research Ethics Committee has reviewed and approved this study.

Who can I approach with questions?

For any questions or queries, you can also contact the following person(s) at the department involved in this study:

- Mr Marc Moncrieff (Consultant Plastic Surgeon)
- Dr Jennifer Garioch (Consultant Dermatologist)

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After completion of the first questionnaire, please return it to us in the stamped-addressed envelope to: **Mr Marc Moncrieff** who can be reached at the above address and will answer any questions that you may have at any time concerning details of the procedures involved in this study.

You will receive a copy of this form.

Thank you for considering this study.