The Newcastle upon Tyne Hospitals
NHS Foundation Trust

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Participant Information Leaflet

STUDY TITLE: Liver Fibrosis in Psoriasis (LFP) Study

FULL TITLE: Investigation of the prevalence of liver fibrosis in patients with psoriasis using Transient Elastography and evaluation of the relationship between liver fibrosis and risk factors for liver fibrosis including methotrexate.

We would like to invite you to participate in a research project about the assessment of liver health in psoriasis.
Before you decide whether or not you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information.

Purpose of the research

Liver damage is thought to be more common in patients with psoriasis based on previous small observational studies. Several risk factors are associated with liver disease in this group of patients. This includes severity of psoriasis as inflammation has been linked to liver disease. Other risk factors include alcohol intake and obesity. When psoriasis is not controlled with creams, the first systemic medication of choice is methotrexate. There have been concerns that this medication can lead to liver damage or worsen the liver health of psoriasis patients however currently there is no strong evidence to confirm this.

Several tests are currently used by dermatologists to monitor the liver health of patients with psoriasis. These include blood tests to measure liver enzymes. However these tests are not very accurate at detecting liver damage. Taking a sample directly from the liver is no longer routinely used to diagnose liver damage as it is invasive and has many risks. A scan (Fibroscan) similar to an ultrasound can be used to measure how elastic or stiff the liver is. If the liver is stiff this indicates that some damage has occurred. This test is now increasingly used to diagnose liver damage.

Aim of the research

This study aims to investigate the prevalence of liver damage in patients with psoriasis using a Fibroscan and aims to evaluate the relationship between liver damage and methotrexate in addition to all other risk factors associated with liver disease . In addition, the relationship between the outcome of the Fibroscan and other simple tests such as blood tests currently used for monitoring of liver health will be assessed.

The overall aim is to use the information gained from this study to determine the number of participants required for a larger study to investigate factors influencing liver damage in this group of patients and to determine whether or not methotrexate is an important contributor to liver damage.

Ultimately a risk prediction model will be built to enable dermatologists to predict the risk of liver fibrosis in patients with psoriasis and more accurately assess which patients are suitable to commence and continue treatment with methotrexate.

Why have I been chosen?

You have been identified as a patient who is eligible for this study as you have chronic plaque psoriasis.

Do I have to take part?

No, taking part is entirely voluntary and your decision will have no consequences. You clinical care will not be affected by your decision to participate or not to participate.

What will happen to me if I take part?

We will ask you to read and sign a consent form. You will be asked to complete simple questionnaires relating to your liver health. A Fibroscan will be requested for you if you have not undertaken this test within 12 months of recruitment. A blood test will be taken as part of your liver health assessment during your clinic visit. Your weight and height will also be measured.

Will my taking part in the study be kept confidential?

Yes, when you consent to take part in the study you will be assigned an anonymised study number.

What will happen to my data, samples and the results of the research study?

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Newcastle upon Tyne Hospitals NHS Foundation Trust will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting the Research team on 0191 2823568.
The Newcastle upon Tyne Hospitals NHS Foundation Trust will collect information from you for this research study in accordance with our instructions.

The Newcastle upon Tyne Hospitals NHS Foundation Trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from The Newcastle upon Tyne Hospitals NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The Royal Victoria Infirmary research team will pass these details to The Newcastle upon Tyne Hospitals NHS Foundation Trust along with the information collected from you. The only people in The Newcastle upon Tyne Hospitals NHS Foundation Trust who will have access to information that identifies you will be people who need to contact you to send you further instructions or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS

number or contact details.

The study results will be published in national and international medical journals. You will not be identified in any reports or publications. A lay summary of the results will be produced when the data is available and can be provided to participants upon request. It will also be available to the members of the team overlooking the appropriate conduct of the study.

Who has reviewed the study?

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 given approval by a Research Ethics Committee (REC REF: 20/NE/0039).

What will happen if I wish to withdraw from the study?

You can withdraw from the study at any time. I you wish to do so, you only need to notify the research team. Any data collected about you may be used in the study analysis unless you also withdraw the consent to use the data.

How do I complain if I wish to do so?

If you have a complaint about the study you can speak to the research staff or the Principle Investigator of the study. The telephone number is 0191 2823568. If you are still unhappy you can contact the Patient Advice and Liaison Service (PALS) office. PALS is open on all weekdays except Bank Holidays on a drop-in basis. A messaging service is available out of hours. Tel: 0800 0320202, email: northoftynepals@nhct.nhs.uk, Text/SMS: 01670511098.

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:
Telephone: 0191 223 1382 or 0191 223 1454
Email: patient.relations@nuth.nhs.uk
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
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NE7 7DN

Who is organising and coordinating the research?

This research is being funded by Psoriasis Association. The research is being coordinated and sponsored by the Dermatology Department at the Royal Victoria Infirmary.

Principal Investigator

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