



UK FSHD Patient Registry

**Principal Investigator/Data Controller: Dr Chiara Marini Bettolo,
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Information for patients

You are being invited to take part in a research database. Before you accept or decline the invitation, it is important for you to understand why the research is being done and what it will involve. Please read the following information and discuss it with relatives, friends and your GP, if you wish. If there is anything that is not clear, or if you have any further questions, please ask us (our contact details are printed on page 3).

Take time to decide whether you would like to take part, or not.

You are being invited to take part in this research database because you have a rare neuromuscular disease known as Facioscapulohumeral Dystrophy (FSHD) and we are trying to get more information on patients, like you, with this condition.

The aim of this research is to establish a database, which will be computer record containing information about you and your condition. Having a computer database of patients with FSHD means that we can easily find groups of patients from all over the UK, who may be able to take part in clinical trials to help, develop new treatments. The database will contain all the information that researchers will need, including each patient's diagnosis and other key details of their disease.

The project team (data controller and data processor) are based at the John Walton Muscular Dystrophy Research Centre at Newcastle University and are responsible for the registry. The project is part of the TREAT-NMD neuromuscular network and the project is supported by Muscular Dystrophy UK (MDUK), as well as many health professionals across the UK.

Before you consider registering your details, it is important that you understand what is involved and what will be done with the information you provide. This form contains answers to some of the questions you might have on the database. At the end of the form, and after you have had some time to think about it, we shall ask if you wish to register. If you do, we shall ask you to sign a consent form saying that you agree to join. If you have any questions please contact us before signing the consent form (contact details on page 3). It is also possible for you to register via the internet on the secure site: www.fshd-registry.org.

How will I benefit from registering?

This database aims to benefit patients living with FSHD. We will make contact with you when we are able to offer new treatments for your condition or to ask you to help assess possible new treatments (clinical trials). By holding secure records of your clinical details we will be able to decide whether or not such trials would be suitable for you. You will not receive any payment or any other financial benefit as a result of joining the database. The results of research arising from the database may have business potential (if for example utilised by a pharmaceutical company to develop a new drug) but you will not

receive financial benefits from such development. Nevertheless, there may be other benefits to joining, including the following:

- We will inform you about suitable clinical trials that you might wish to join.
- If you wish, we will update you on any new developments on your condition.
- The details collected will also provide information for doctors interested in the best standards of care for your disease.

Data linkage to the Newcastle MRC Centre Biobank for Rare and Neuromuscular Diseases

The Newcastle MRC Centre Biobank for Rare and Neuromuscular Diseases is a repository that creates a 'bank' of samples including: DNA and cells obtained from blood, urine, saliva, skin, muscle and nerve from healthy people as well as from those with diagnosed diseases, for use in future research. A biobank is the term used to describe a collection of samples stored for research.

We are working to anonymously link your registration on the DM national registry to samples contained in the biobank should these be available. Linking the registry data with data that may be held in the biobank will help enhance the information available to researchers when accessing the samples or the registry, therefore facilitating research. Data would be linked via a unique identifier which ensures confidentiality is preserved.

I want to be involved in a clinical trial. If I register, is this guaranteed?

No. Although one of the main aims of this database is to make it easier for patients to be recruited for clinical trials, there is no guarantee that registering your details will mean you will be automatically approached to take part in a clinical trial. Doctors organising a clinical trial will review the details you have given and if the trial appears to be suitable for you they will invite you to join. All patients invited to join a particular trial will then be assessed in greater detail and at this stage it may be clear that other developments in your health or details not recorded on the database mean that the trial is not a suitable one for you.

Will information about me be kept confidential?

All information we receive from you will be treated confidentially. The information will be converted into code and stored on a secure computer in the UK. We make every effort to ensure your data is kept safe but we remind you to be vigilant when entering information online. Details of your specific diagnosis as well as personal information (name, age, address, gender) will be stored on the database. This information is all required to enable us to match you with the criteria, however only members of Dr Marini Bettolo's team given specific permission by her, will be allowed to look at this information. If we publish any research or other documents based on information from the database, this will not identify you by name.

If you would like more information about how we manage personal data more generally, including your rights under law, and the contact details of the University's Data Protection Officer, please see our website: <https://www.ncl.ac.uk/data.protection/>.

Do I have to join the database and can I withdraw if I change my mind?

Joining the database is voluntary. Should you wish to withdraw your information from the database you will be free to do so at any time without having to provide any explanation. If you wish to withdraw, you should get in touch with the staff in charge of the database.

Contact details are provided below. Joining or leaving the database will in no way affect the care you receive for your condition.

How will my data be used?

The main aim of us asking you to be part of the registry is to help recruitment into clinical trials. However the data may also be used to learn more about people with FSHD. The answers information you provide may be used to help researchers design future investigations.

How will my details be updated?

You will be able to update your details via the online registry platform. We will also ask you for updated information on an annual basis (via an email). You can contact us at any time if you need to amend your details. We also ask you to inform us if there are any major changes in your details that might occur in the period between updates, for example a change of address or major change to your condition. You are free to have your information withdrawn from the database at any time.

Who will have access to my data?

Staff in charge of the registry will have access to your data to obtain information necessary to a project and are able to contact you, for example to inform you about an upcoming clinical trial. In addition, the doctor that you choose during registration (optional) will have access to your data, this is necessary because he/she will fill out the second part of the registration questionnaire.

Third parties wishing to have access to data in the UK FSHD Patient Registry (such as researchers or companies planning clinical trials or conducting research on new therapies) will only have access to anonymous information identifiable only by a code. Before they are granted access even to this anonymous information, they will have to have the approval of an Ethics Committee and the registry steering committee.

Who is funding the research?

The project is funded by MDUK. No additional payments will be received by Dr Marini Bettolo, or other members of the research team, for adding your child's details on to the database.

Who has reviewed this project?

This research has been reviewed by North East – Newcastle and North Tyneside 1 Research Ethics Committee who have decided they are happy for us to go ahead with the study.

What if I have any concerns?

If you have any concerns or other questions about this study or the way it has been carried out, you should contact the principal investigator:

Dr Chiara Marini Bettolo

Tel: 0191 241 8606

Email: Chiara.Marini-Bettolo@newcastle.ac.uk

If you feel that you have been treated unfairly throughout the research, or would like to comment on the conduct of any aspect of this research, please contact the Patient Advice and Liaison Service (PALS) 0800 0320202.

If you are concerned about the management of your personal data, a complaint may be lodged with the Information Commissioner's Office, UK: <https://ico.org.uk>.

Thank you for taking the time to read this information sheet