



Patient Information Leaflet

Study title: A Population-Based Epidemiologic Study of Adult Neuromuscular Disease in the Republic of Ireland

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You are being invited to take part in a clinical research study to be carried out at Beaumont Hospital and Cork University Hospital.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study and a decision not to take part will not effect on your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

There have been no previous studies in the Republic of Ireland looking at how many patients there are with different diseases of the muscles and nerves. We call these conditions 'neuromuscular conditions'. In this study we would like to find out exactly how many patients there are with these conditions. This will help us to form lists of patients and find out how common these conditions are; we call lists like these 'Registries'. These registries will be a useful way of ensuring that patients can be kept informed about the latest information that might be relevant to their disease including the latest treatment options. Sometimes there are new drugs available to treat these conditions which have to be given first in what we call a 'clinical trial'. Therefore these registries will facilitate the inclusion of Irish patients with neuromuscular conditions in clinical trials of new drug treatments for their diseases.

Who is organising and funding this study?

This research study is organised by Neurology Consultants at both Beaumont Hospital and Cork University Hospital. The study is funded by Pharmaceutical Company Genzyme who have given a 2 year grant to employ a full time 'Specialist Registrar Research Fellow' to carry out this research under the supervision of Professor Orla Hardiman (Beaumont Hospital) and Dr Aisling Ryan (Cork University Hospital). This Research Fellow is Dr Stela Lefter; she works jointly between the Cork and Dublin neuromuscular centres and will register for a higher degree. None of the researchers will be paid to recruit patients.

Why am I being asked to take part?

We are asking you to be part of this study because you have a neurological condition which affects the nerves or muscles.

Why is the study being carried out?

This study started in January 2012 and will finish in 2 year time. This study takes place at Beaumont Hospital Neuromuscular Centre and Cork University Hospital Neuromuscular Centre. The aim is to collect information about the frequency of disorders of nerve and muscle in Ireland. We anticipate approximately 1300 patients will participate in this study.

What will happen to me if I agree to take part?

This study started in January 2012 and will finish in 2 year time and takes place at Beaumont Hospital Neuromuscular Centre and Cork University Hospital Neuromuscular Centre. If you decide to participate in this study, an appointment will be made for you to visit and be reviewed by Professor Hardiman and Dr Stela Lefter at the Specialist Neuromuscular Clinic in Beaumont Hospital / or by Dr. Aisling Ryan and Dr. Stela Lefter at the Specialist Neuromuscular Clinic in Cork University Hospital. Alternatively, Dr. Stela Lefter can visit you at home. **Once you have signed the consent form, you will be included in the Registry.** The data collected in the registry will contain your personal and medical information, including the results of assessments and genetic tests. Your clinical details will be stored on the Register, but these will be codified, and the Register will be retained in password protected file in a locked facility. The information about you which will be placed on the registry will be collected from you during your visit to Beaumont Hospital / Cork University Hospital, and from your medical records. There are plans to develop the registry into a number of separate registries for specific neuromuscular diseases and we may use the information collected in the registry for future research studies. If you wish, Professor Hardiman will be happy to follow you up long term in the Specialist Neuromuscular Clinic at Beaumont Hospital. Likewise, Dr. Ryan is happy to follow you up long term in Cork University Hospital. This study does not involve the testing of any new drug treatments and thus does not involve any risk to you. Also, this study does not involve the taking of any blood samples.

What other treatments are available to me?

This study is not a treatment study. Whether you take part or not in this study, your treatment will not differ.

What are the benefits?

There are no direct benefits available to you for participation in this research. Hopefully, these registries will be a useful way of ensuring that patients like you can be kept informed about the latest information that is relevant to your disease including the latest treatment options or clinical trials of new drug treatments.

What are the risks?

There are no conceivable risks to your health associated with participating in this research.

What if something goes wrong when I'm taking part in this study?

We do not anticipate anything will go wrong as there is no treatment or procedures involved in this trial.

Will it cost me anything to take part?

The study will not involve any cost to you apart from travelling to Beaumont or Cork University Hospital Neuromuscular clinics. Unfortunately, we are not in a position to reimburse your travel expenses.

Is the study confidential?

The information that we collect from this research project will be kept confidential. If you are a patient of Beaumont Hospital or Cork University Hospital, then your medical records there will be reviewed by the researchers. Information about you that will be collected during the research will be put away and no-one but the named researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is. We will not be sharing your identity or number with anybody else. If you wish us to do so, we will contact your GP and specialist with the results of the study. The results of this study will be used to produce a scientific paper which may be published. Copies of the scientific paper will be kept at the Beaumont Hospital should you wish to access it in the future.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future. If you need any further information now or at any time in the future, please contact:

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