The Newcastle Upon Tyne Hospitals NHS
NHS Trust

The Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN

Research into heart rhythm disturbances in patients with Duchenne or Becker muscular dystrophy [IRAS: 252541]

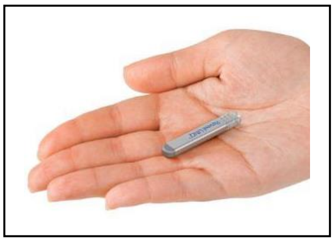
We invite you to take part in a research study...

- Before you decide whether to take part, 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. Discuss it with friends and relatives, if you wish.
- Your are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors.
- Ask us if there is anything that is not clear or if you would like more information.

Important things you need to know ...

- We want to find out whether patients whose hearts are weakened in their pumping ability because of Duchenne or Becker muscular dystrophy become 'irritable' - as shown by frequent abnormal 'extra beats' and/or 'short runs' of abnormal fast or abnormal slow beating, without this being necessarily obvious to patients.
- The best way to decide whether the heart is behaving in this way is to monitor it continuously (24/7) by means of a **small electronic 'chip' implanted under the skin**. This small device 'watches' the heart rhythm continuously and automatically records certain types of speed-abnormalities. It then transmits anything it has recorded automatically to a base-station at the Freeman Hospital - using a home phone line and a transmitter individualised to your device.
- Any recordings transmitted are seen and assessed by cardiology physiologists throughout the working week for their importance and the results passed to the research team - who can notify you, if appropriate. In this way there is no need for you to return repeatedly to the hospital to allow the research team to see whether abnormal heart beating has happened or not. This 'chip'-device has been used in various clinical contexts for many years.
- We also want to undertake a very **detailed scan of the heart** (cardiac MRI-scan) once in some patients - to measure heart function and to study the pattern of scars that form in patients with muscular dystrophy. This scan involves injection of a special substance (Gadolinium) into a vein in your arm to be able to assess heart scaring.
- Therefore, taking part in the study would involve **either one or two extra visits** – one, if only having the ‘chip’ implanted under local anaesthesia without the detailed heart scan (MRI) and two visits, if having both the ‘chip’ implant and an MRI scan performed. Each procedure takes about an hour.
- At the end of the six month study period, you will have the option of having the 'chip' removed or you can leave it in place until its batteries are running down - typically after about a further two years. Recordings made during that longer period would not form part of the research study but would be interpreted clinically as part of your standard care arrangements.

Are there any possible discomfort or side-effects ...?



- Taking part in this research is very safe.
- Implanting the 'chip' involves injecting local anaesthetic to numb a small area on the front of your chest. The implant involves minor discomfort at the time and until the site heals in the days afterwards. In very rare instances, the implant site can become infected and this would require the device to be removed to allow healing.

- The detailed heart scan is performed in an MRI-department in Newcastle upon Tyne, takes about an hour and does not expose you to any X-rays or other radiation. To allow scars in the heart to be seen, requires injection of a special substance (eg: Gadolinium) into a vein in your arm. There are very rare reports of patients having serious 'reactions' (adverse effects) later on to this substance. However, scans involving Gadolinium injection are performed routinely many times every week without complications in patients having this scan for clinical reason.

Why am I being asked to take part ..?

- You are being invited to take part because we know that your heart is affected by Duchenne or Becker muscular dystrophy gene abnormalities and you are already taking heart medications to treat this.
- It is patients, known to have reduced heart pumping function, that are needed for this particular research study.

Who is conduction this research?

The research team is being led by Dr John Bourke, Consultant Cardiologist. Contact details are: Department of Cardiology, Freeman Hospital, Newcastle upon Tyne NHS Hospitals Foundation Trust, Newcastle upon Tyne, NE7 7DN. - **Phone: (0191) 213 7131**

If you have a concern or wish to make a complaint ....

You can do so by contacting Dr Bourke directly or, if you prefer, by contacting the Patient Advice and Liaison Service:
Freephone: 0800 032 0202 - or - Text: 01670 511 098 - or - email: northoftynepals@nhct.nhs.uk

What to do next ...

If you would prefer not to participate or have any doubts about taking part in this research, you should **say NO**. You will not be required to give any explanation as to why you have made this decision and, be assured that, your decision will not affect the standard of care you receive afterwards in any way and we will not approach you again on this matter.

If you wish to take part in this research – either just having the 'chip' implanted or having both 'chip-implant' and heart scan, simply return the attached reply to the person who sent / gave it to you. Before you do this, please **check that your address is correct** and **add your telephone number** in the space provided so that we can make further contact with you about this project.

Even if you say YES now, it is still your right to say NO later when we contact you, without having to give any explanation as to why you changed your mind. If you have any questions about this research, a member of the research team will be happy to answer them for you. Contact details are listed above.

Will I get to hear the results of the study, when it has finished ...?

Yes, we plan to communicate the main findings in an 'easy to understand' summary to each participant once the results have been analysed. It usually takes about six months from the time the last patient has completed follow up for the findings to become available

General Data Protection Regulation (GDPR) **in relation to your personal data and this 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 and/or your medical records in order to undertake this study and will act as the data controller for this research project. 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 five years after the study has finished (or longer only if required by legislation or research governance regulations].

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 contacting nuth.dpo@nhs.net

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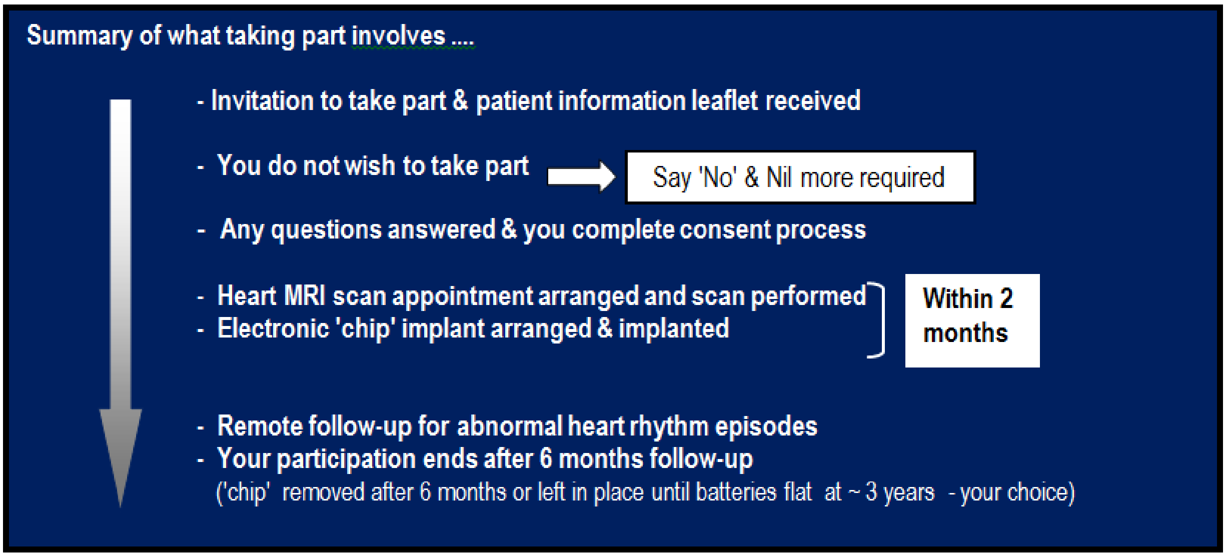
- Thank you for taking the time to read this patient information sheet –



Summary of what taking part involves ....

- **Invitation to take part & patient information leaflet received**
- **You do not wish to take part** → Say 'No' & Nil more required
- **Any questions answered & you complete consent process**
- **Heart MRI scan appointment arranged and scan performed**
- **Electronic 'chip' implant arranged & implanted**

Within 2 months

- **Remote follow-up for abnormal heart rhythm episodes**
- **Your participation ends after 6 months follow-up**
  ('chip' removed after 6 months or left in place until batteries flat at ~ 3 years - your choice)

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Name (print)

Address (print & include post code):

Preferred telephone contact number:

- **I wish to take part in this research please contact me about 'next steps'** (tick if applies): ☐

- **I do not wish to take part in this research - please do not contact me** (tick if applies): ☐

- **I would like to hear more about the research to make up my mind, Please phone me** (tick if applies): ☐

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Now return your response to the person who gave it to you or by email:

Email: louise.quinn4@nhs.net or phone after 5 pm 0191 - 213 7131 (leave a message)

or by post to:

Cardiology Research Nurse Office, Level 1, Freeman Hospital, Newcastle upon Tyne, NE7 7DN