Will My Privacy Be Protected?

All personal and medical information will be kept strictly confidential. Information about your health while you are enrolled in HERCULES and ATLAS will be kept anonymous and any identifying information will not be used. For further information about how your privacy will be protected, please see the study related Informed Consent Form (ICF).

If you have questions about the study, please talk to the Study Doctor.

_____

HERCULES Doctor's Name:

_____

Study Coordinator's Name:

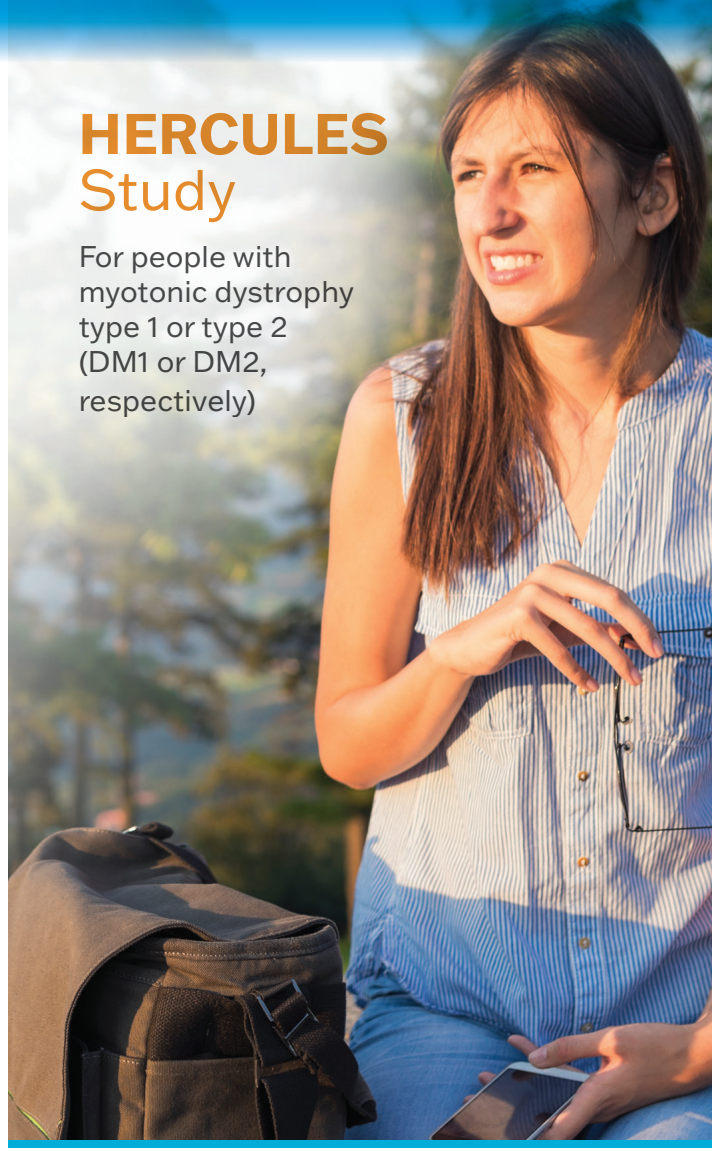
_____

Office Phone Number:

Scan this code using a QR reader on your smartphone to visit **www.MyotonicDystrophyStudy.com** for more information and to see if you qualify.

HERCULES Study

For people with myotonic dystrophy type 1 or type 2 (DM1 or DM2, respectively)



HERCULES

Patient Information Pamphlet

What is HERCULES?

HERCULES is a clinical research study evaluating if an investigational medication, called mexiletine prolonged release (PR), is safe and effective in alleviating muscle stiffness and improving daily activity and quality of life in people diagnosed with myotonic dystrophy type 1 or type 2 (DM1 or DM2, respectively).

The study will include a total of 96 patients across different countries in Europe and the United Kingdom.

About Myotonic Dystrophy

Myotonic dystrophy is a genetic condition that causes progressive muscle weakness and myotonia, which is an inability to relax muscles after contraction.

Currently, there is no cure or genetic treatments for myotonic disorders. Mexiletine (NaMuscla®) has been approved for easing the symptoms of myotonia in adults with non-dystrophic myotonic (NDM) disorders, thus improving quality of life. It is a safe and efficacious treatment.

While mexiletine is approved, there is still limited information about its safety and effectiveness in people with DM1 and DM2. HERCULES will evaluate how mexiletine PR impacts quality of life in people with myotonia.

Who Can Join?

You may be able to join the HERCULES study if you are:

- At least 16 years of age*
- Genetically diagnosed with DM1 or DM2

**Participants under the age of 18 will need approval from a responsible adult to participate.*

What Will My Participation Involve?

If you qualify and agree to participate in this study, you will be randomly chosen to receive either the investigational drug (mexiletine PR) or a placebo (a treatment with no active ingredient). You have an equal chance of receiving either mexiletine PR or placebo. HERCULES is a blinded study - neither you, nor your study doctor, will know which treatment you are receiving.

Participants will take either mexiletine PR or placebo for 6 months orally (by mouth). Participants will then have the option to participate in a follow-up study, called ATLAS, for a further 18 months.

In the ATLAS study, all participants will receive treatment with mexiletine PR and benefit from comprehensive safety assessments during their time in the study. ATLAS will evaluate long-term safety and effectiveness of mexiletine PR. Your health and safety will be closely monitored throughout both studies.

During your participation in HERCULES, you will be required to attend 6 appointments and 2 telephone calls with the study team.

During study visits, the study team will:

- Ask about your health and how you have been feeling
- Conduct study-related examinations
- Test your blood and urine
- Ask you to complete questionnaires on your symptoms
- Provide you with study medication and instruct you how to take and track your study medication use

Qualified patients will receive study-related examinations and medication at no cost.

Your participation in both studies is voluntary. You are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. You can discuss regular medical care with the study doctor.

Why Should I Participate?

While we do not know the outcomes of the study, there may be potential improvement to your health. Mexiletine has been used as an antimyotonic treatment for several decades and it is considered for treatment of myotonia.

In addition, you are contributing to the advancement of medical knowledge and potentially helping to improve treatments for yourself and others in the future by participating in this study.

HERCULES and ATLAS will provide information on the safety and effectiveness of mexiletine's PR formulation in people with DM1 and DM2.

What is an Informed Consent Form (ICF)?

The Informed Consent Form (ICF) describes the study and any potential risk or benefits of participation. The study team will answer any questions you may have. By signing the ICF, you agree to participate in the study.