

Do you have Myotonic Dystrophy Type 1 (DM1) or Type 2 (DM2)?

Learn more about a clinical study evaluating the safety and effectiveness profile of mexiletine prolonged release (PR), in alleviating muscle stiffness and delayed relaxation (myotonia), supporting daily activities and quality of life.

HERCULES is a clinical study evaluating the safety and effectiveness profile of an investigational medicine, called mexiletine prolonged release (PR), in alleviating muscle stiffness and delayed relaxation (myotonia). This treatment aims to support daily activities 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 at several hospitals ("study sites") across several different countries in Europe (including the United Kingdom). Learn more at: <https://myotonicdystrophystudy.com>.

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

- are aged 16 years or older*,
- have a genetically confirmed diagnosis of DM1 or DM2,
- weigh 45 kg or more,
- can walk independently for 10 metres (with a cane, walker or orthoses, if needed),
- are not pregnant.

** below 18 years, an approval from a responsible adult is needed.*

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

Participants will be randomly chosen to receive either mexiletine PR or a placebo (a treatment with no active ingredient). The participants have an equal chance of receiving either mexiletine PR or placebo for six months orally (by mouth). Each person's health and safety will be closely monitored throughout the study.

Mexiletine (NaMuscla®) is already approved for easing the symptoms of myotonia in adults with non-dystrophic myotonic disorders (NDM). It has a well-established safety and effectiveness profile.

While mexiletine is approved to treat NDM, there is still limited information about its safety and effectiveness in people living with DM1 and DM2.

HERCULES will evaluate how mexiletine PR impacts quality of life in DM1 and DM2 patients with myotonia.

After completion of the HERCULES study, participants may enter the follow up study ATLAS. ATLAS is an open-label extension study in which all participants will receive mexiletine in a prolonged release formulation.

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



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