The Efficacy and Safety of Once Daily Mexiletine PR in Patients With Myotonic Dystrophy Type 1 and Type 2

NCT06523400

Status	RECRUITING
Phase	Phase 3
Sponsor	Lupin Ltd.
Enrollment	176 participants

Key Eligibility Criteria

Inclusion (11)

- DM1 or DM2 diagnosis confirmed genetically;
- Ability to comprehend and willingness to sign an informed consent (ICF) or ICF of the parent(s)/legal guardian and written assent from the patient (if patient \< 18 years of age);
- Ability to understand the study requirements including intention to stay in the study until the end-of-study visit at 26 weeks of treatment;
- Male or non-pregnant female e16 years of age;
- Body Mass Index (BMI) of 18.5 kg/m2 to 30 kg/m2, and weight e45 kg;

... and 6 more (see full listing online)

Exclusion (28)

- Are pregnant or lactating;
- Have any one of the following medical conditions: uncontrolled diabetes mellitus, cancer other than skin cancer less than five years previously (e.g., basal-cell carcinoma (BCC) and squamous-cell carcinoma (SCC) of skin allowed), multiple sclerosis, seizure disorders, or other serious medical illness;
- Severe renal impairment (glomerular filtration rate (GFR) \< 30 mL/min);
- Medical conditions which could interfere with muscle function such as infections, trauma, fractures, or planned surgery;
- Medical conditions that could affect hand functioning including but not limited to rheumatoid arthritis, Dupuytren's contracture, hand deformity, etc.;

... and 23 more (see full listing online)

Locations (7 total)

Laboratory for Muscle Diseases and Neuropathies, Leuven, Belgium
Aarhus University Hospital, Aarhus, Denmark
Ludug-Maximilians University, München, Germany
... and 4 more locations