

Clinical Trial of Mexiletine Hydrochloride for Spinal and Bulbar Muscular Atrophy

NCT06862596

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Masahisa Katsuno
Enrollment	68 participants

Key Eligibility Criteria

Inclusion (5)

- Male patients with a CAG repeat count of 38 or more for the androgen receptor gene in genetic testing and a confirmed diagnosis of SBMA
- Patients with muscle weakness (limb weakness and atrophy, or bulbar palsy) due to lower motor neuron lesion
- Patients with a total ALSFRS-R score of e 24 and d 42 at screening
- Patients who are at least 18 years old and less than 80 years old at the time of consent
- Patients who give their voluntary written consent after having received adequate information on this study (However, if the patient is unable to sign the consent form due to the condition of the disease, a person equivalent to a legal representative must be present to provide written explanation, the prospective candidate must verbally consent to participate in the study, and a person equivalent to a legal representative must sign the consent form on behalf of the patient. The person who is to be the legal representative may sign the document on his/her behalf, noting the circumstances and his/her relationship to the subject.)

Exclusion (16)

- Patients who have participated or are participating in a clinical trial within 12 weeks prior to enrollment
- Patients with a history of hypersensitivity to any component of this drug product
- Patients with a conduction disturbance (such as second- or third-degree atrioventricular block without a pacemaker, or left bundle branch block)
- Patients with Brugada-type ECG
- Patients with severe heart failure or heart disease (myocardial infarction, valvular disease, cardiomyopathy, etc.)

... and 11 more (see full listing online)

Locations (5 total)

Tokyo University Hospital, Bunkyo City, Japan
Chiba University Hospital, Chiba, Japan
Hokkaido University Hospital, Sapporo, Japan
... and 2 more locations

<https://clinicaltrials.gov/study/NCT06862596>

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