

# The Efficacy and Safety of Metoprolol as add-on Treatment to Standard of Care in Preventing Cardiomyopathy in Patients With DMD

NCT05066633

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Status	RECRUITING
Phase	Phase 3
Sponsor	Medical University of Gdansk
Enrollment	150 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Subject's parent(s) or legal guardian(s) has (have) provided written informed consent, where applicable, prior to any study-related procedures; participants will be asked to give written or verbal assent according to requirements (>16 years old)
- Stated willingness to comply with all study procedures and availability for the duration of the study
- Ability to take oral medication and be willing to adhere to the study intervention regimen
- Subject has confirmed diagnosis of DMD, as defined as clinical picture consistent with typical DMD and: i) Dystrophin immunofluorescence and/or immunoblot showing complete dystrophin deficiency, or ii) Identifiable mutation within the DMD gene (deletion/duplication of one or more exons), where reading frame can be predicted as 'out-of-frame' or, iii) Complete dystrophin gene sequencing showing an alteration (point mutation, duplication, other) that is expected to preclude production of the dystrophin protein (i.e., nonsense mutation, deletion/duplication leading to a downstream stop codon)
- Taking ACEi treatment at minimum required doses for at least 30 days

### Exclusion (8)

- Current or previous permanent use of any beta-blocker medication
- Treatment with another investigational drug or other intervention within 3 months prior to screening
- Clinically significant bradycardia at rest or by Holter ECG, based on age and sex adjusted normal values, atrioventricular block higher than first degree at rest, or second degree Wenckebach at night, pauses longer than 2.5 seconds
- Presence of pacemaker or ICD
- Clinical signs or symptoms of heart failure
- ... and 3 more (see full listing online)

## Locations (1 total)

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University Clinical Centre in GdaDsk, Clinic of Paediatric Cardiology and Congenital Heart Defects, Gdansk, Pomeranian Voivodeship, Poland

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<https://clinicaltrials.gov/study/NCT05066633>

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