

# Givinostat in Duchenne's Muscular Dystrophy Long-term Safety and Tolerability Study

NCT03373968

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Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Italfarmaco
Enrollment	206 participants

## Key Eligibility Criteria

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### Inclusion (11)

- Must have participated in one of the previous studies with GIVINOSTAT in DMD and have attended the End of Study Visit or must have been screened in study DSC/14/2357/48 and met:
  - had a baseline vastus lateralis muscle fat fraction (VL MFF) assessed by MRS in the range  $\leq 5\%$  or  $> 30\%$ , i.e. included in "off-target" group,
  - never been randomized because, the enrollment in the off target group was completed.
  - Aged  $\geq 6$  years old;
  - Are able to give informed assent and/or consent in writing signed by the subject and/or parent/legal guardian (according to local regulations);
- ... and 6 more (see full listing online)

### Exclusion (13)

- Use of any pharmacologic treatment, other than corticosteroids, that might have had an effect on muscle strength or function within 3 months prior to be enrolled in this study (e.g., growth hormone); Vitamin D, calcium, and any other supplements will be allowed;
  - Use of any current investigational drug other than Givinostat;
  - Have presence of other clinically significant disease, which, in the Investigator's opinion, could adversely affect the safety of the subject, making it unlikely that the course of treatment or follow-up would be completed, or could impair the assessment of study results;
  - Have a diagnosis of other uncontrolled neurological diseases or presence of relevant uncontrolled somatic disorders that are not related to DMD;
  - Have platelets count, White Blood Cell and Hemoglobin at screening  $<$  Lower Limit of Normal (LLN)\* (for abnormal screening laboratory test results ( $<$ LLN), the platelets count, White Blood Cell and Hemoglobin will be repeated once; if the repeat test result is still  $<$ LLN, then exclusionary);
- ... and 8 more (see full listing online)

## Locations (39 total)

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University of California - Davis Medical Center - Devis Physical Medicine & Rehabilitation, Sacramento, California, United States  
Rady Children's Hospital center - UCSD Department of Neuroscience, San Diego, California, United States  
Connecticut Children's Medical Center, Neurology Division, Hartford, Connecticut, United States  
... and 36 more locations

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<https://clinicaltrials.gov/study/NCT03373968>

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