

Phase 3 PolarisDMD Trial [TERMINATED]



Phase III Study of Edasalonexent in Boys With Duchenne Muscular Dystrophy (PolarisDMD)

Hub Summary

PolarisDMD is a global, placebo controlled, Phase 3 trial for edasalonexent (CAT-1004). Edasalonexent is an NF-κB inhibitor, which could provide an alternative to steroids. Edasalonexent has been shown to preserve muscle function and substantially slow Duchenne disease progression in the MoveDMD trial.

This trial will evaluate the efficacy and safety of edasalonexent in patients with DMD, and is intended to support an application for commercial licencing of edasalonexent.

To receive up-to-date information about this trial, please sign up to the [Catabasis newsletter](#).

Study Number: NCT03703882

Description by Catabasis Pharmaceuticals

The PolarisDMD study is a global Phase 3 study to evaluate the efficacy and safety of edasalonexent (CAT-1004) in boys 4 to 7 years old affected by DMD.

Two boys will receive edasalonexent for each boy that receives placebo and after 12 months, all boys are expected to receive edasalonexent in an open-label extension. Edasalonexent is an oral therapy.

Edasalonexent is a potential foundational therapy that is being developed for all patients affected by DMD. Edasalonexent inhibits NF-κB, which drives inflammation, fibrosis and muscle degeneration and suppresses muscle regeneration.

At this time, the UK sites are at capacity however if you are interested in trial participation, please contact DMDtrials@catabasis.com

Primary Outcome Measures

- Change in the North Star Ambulatory Assessment score after 12 months of treatment with edasalonexent compared to placebo

Secondary Outcome Measures

- Timed function tests time to stand, 4-stair climb and 10-meter walk/run
- Additional assessments of growth, cardiac and bone health

Can I take part?

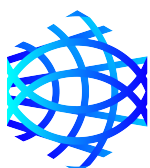
Inclusion Criteria

- ✓ Age 4 to 7 (up to 8th birthday)
- ✓ Able to complete timed function tests

Exclusion Criteria

- ✗ Not on corticosteroids for at least 6 months
- ✗ Not on other investigational therapies for at least 1 month

For contact details and to find out more, please refer to dmdhub.org.



**Duchenne
UK**

PDF created on 25/08/2025.

Trial Status Trial terminated



UK Locations

London - Evelina, Trial complete/terminated,
London - GOSH, Trial complete/terminated,
Bristol, Trial complete/terminated, Manchester,
Trial complete/terminated, Temple Street, Trial complete/terminated



Trial Sponsor

Catabasis Pharmaceuticals



Phase

Phase 3



Length Of Participation

12 months, followed by optional open-label extension



Recruitment Target

126



Ambulatory

Ambulant



Therapeutic Category

Steroid alternative



Age

4-7 years



Mutation Specific

Non-mutation specific therapies



Muscle Biopsy

No Muscle Biopsy Required



MRI

No

dmdhub.org



DMD HUB