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 edasolonexent (CAT-1004). Edasalonexent is an NF-kB 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 edasolonexent in patients with DMD, and is intended to support an application for commercial licencing of edasolonexent.

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-kB, 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 Join us to end Duchenne

PDF created on 17/04/2021.

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

Age
4-7 years

Mutation Specific
Non-mutation specific therapies

Muscle Biopsy
No Muscle Biopsy Required

MRI
No

Phase
Phase 3

Length Of Participation
12 months, followed by optional open-label extension

Recruitment Target
126

Ambulatory
Ambulant

Therapeutic Category
Steroid alternative

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