

Mallinckrodt- MK1441 (BRAVE)



A Multicenter, Randomized, Parallel Group, Double Blind, Multiple Dose, Placebo Controlled Study to Assess the Efficacy and Safety of MNK-1411 in Male Subjects 4 to 8 Years of Age With Duchenne Muscular Dystrophy

Hub Summary

This phase 2 study is designed to assess the safety and efficacy of MNK-1441. The double blind, placebo controlled, multiple dose study will take place in DMD boys between the ages of 4 and 8.

It is thought that MNK-1441 has anti-inflammatory effects which could reduce muscle damage and in-turn delay DMD progression.

Study Number: NCT03400852

Description by Mallinckrodt

This is a multicenter, double blind, placebo controlled, multiple dose study to examine the safety and efficacy of MNK-1411 in male subjects 4 to 8 years of age (inclusive) with Duchenne Muscular Dystrophy (DMD).

Primary Outcome Measures

- 10 metre walk/run (25 weeks)

Secondary Outcome Measures

- NorthStar Ambulatory Assessment
- 4 stair climb
- Rise from supine test
- Quantitative muscle testing

Can I take part?

Inclusion Criteria

- Subjects must have a documented diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by complete dystrophin deficiency (by immunofluorescence and/or immunoblot), or identifiable mutation in the DMD gene where reading frame can be predicated as "out of frame," or complete dystrophin gene sequencing consistent with DMD; AND in the opinion of the Investigator, a typical clinical profile consistent with DMD.
- Subjects taking approved treatments for DMD (by a Health Authority) that target dystrophin gene mutations (eg, eteplirsen or ataluren) may be enrolled in the study if they have been on a stable dose for 30 days prior to the first dose of study drug, and plan to remain on that dose throughout the study

Exclusion Criteria

- Subject has had previous systemic treatment with corticosteroids. Transient previous use of corticosteroids will be evaluated on a case-by-case basis by the sponsor or designee. Inhaled corticosteroids will be permitted if given at a stable dose for the 3 months prior to the first dose of study drug and the subject will remain on that dose throughout the study. The use of topical or intra-articular corticosteroids is permitted during the study.
- Subject has symptomatic cardiomyopathy in the opinion of the investigator.
- Subject is unable to complete the 10 meter Walk/Run test at the Screening and/or Baseline Visit.
- Subject has Type 1 or Type 2 diabetes mellitus.
- Subject has a history of chronic active hepatitis including acute or chronic hepatitis B, or acute or chronic hepatitis C.
- Subject has a history of tuberculosis (TB) infection, any signs/symptoms of TB, or any close contact with an individual with an active TB infection.
- Subject has known immune compromised status (not related to disease/condition under study), including but not limited to, individuals who have undergone organ transplantation or who are known to be positive for the human immunodeficiency virus.

Trial Status

Not yet recruiting

UK Locations

Trial Sponsor

Mallinckrodt

Phase

2

Length Of Participation

48 weeks

Recruitment Target

132

Ambulatory

Ambulant

Therapeutic Category

Steroid alternative

Age

4 to 8 years

Mutation Specific

Non-mutation specific therapies

Muscle Biopsy

No Muscle Biopsy Required

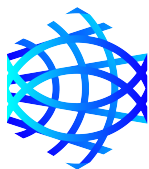
MRI

No

dmdhub.org



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



Duchenne
UK

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