ForPatients
by Roche

Duchenne Muscular Dystrophy (DMD)

Clinical Trial to Evaluate the Efficacy, Safety, and Tolerability of RO7239361 in Ambulatory Boys With Duchenne Muscular Dystrophy

Trial Status	Trial Runs In	Trial Identifier
Completed	13 Countries	NCT03039686 2016-001654-18 WN40227 CN001-016

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Randomized, Double Blind, Placebo-Controlled, Study to Assess the Efficacy, Safety, and Tolerability of RO7239361 in Ambulatory Boys With Duchenne Muscular Dystrophy

Trial Summary:

This is a multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy, safety and tolerability of two different weekly doses of RO7239361 in ambulatory boys with Duchenne Muscular Dystrophy (DMD).

Hoffmann-La Roche
Sponsor

Phase 2/Phase 3
Phase

NCT03039686 2016-001654-18 WN40227 CN001-016
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#6 Years & # 11 Years	No

Inclusion Criteria:

- Diagnosed with DMD by confirmed medical history and genetic testing
- Able to walk without assistance
- Minimum North Star Ambulatory Assessment score of 15 at screening
- Able to walk up 4 stairs in 8 seconds or less
- Weigh at least 15 kg (33 lbs)
- Taking corticosteroids for DMD

Exclusion Criteria:

- Any behavior or mental issue that will affect the ability to complete the required study procedures
- Previously or currently taking medications like androgens or human growth hormone
- Use of a ventilator during the day
- Unable to have blood samples collected or receive an injection under the skin
- Concomitant or previous participation at any time in a gene therapy study

Other protocol defined Inclusion/Exclusion Criteria could apply.