ForPatients

by Roche

Muscular DystrophyDuchenne Muscular Dystrophy (DMD)

Study of an Investigational Drug, RO7239361 (BMS-986089), in Ambulatory Boys With DMD

Trial Status Trial Runs In Trial Identifier

Terminated 2 Countries NCT02515669 WN40226 CN001-006

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 Multi-Site, Randomized, Placebo-Controlled, Double-Blind, Multiple Ascending Subcutaneous Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of RO7239361 (BMS-986089) in Ambulatory Boys With Duchenne Muscular Dystrophy

Trial Summary:

The purpose of this study is to determine the safety and tolerability of RO7239361 in boys with Duchenne Muscular Dystrophy with any genetic mutation.

Hoffmann-La Roche Sponsor	Phase 1/Pl Phase	Phase 1/Phase 2 Phase ———————————————————————————————————	
NCT02515669 WN40226 CN001-006 Frial Identifiers			
Eligibility Criteria:	iers		
Gender Male	Age #5 Years & # 10 Years	Healthy Volunteers	

Inclusion Criteria:

- Diagnosed with DMD
- Able to walk without assistance
- Able to walk up 4 stairs in 8 seconds or less
- Weigh at least 15 kg
- Taking corticosteroids for DMD

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Exclusion Criteria:

- Ejection fraction < 55% on echocardiogram, based on central read
- 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
- Treatment with exon skipping therapies 6 months prior to study start
- Treatment with ataluren or any investigational drug currently or within 5 half-lives prior to study start