ForPatients
by Roche

Spinal Muscular Atrophy (SMA)

Bioavailability and Bioequivalence of Two Risdiplam Tablets in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04718181 BP42066

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:

Risdiplam - A Phase I, Open-Label, Multi-Period Crossover Study to Investigate the Safety, Food Effect, Bioavailability and Bioequivalence of Oral Doses of Two Different Formulations in Healthy Subjects

Trial Summary:

The study is a randomized, single oral dose, crossover study in up to three parts to investigate the relative bioavailability and bioequivalence of two different formulations of risdiplam 5 mg (dispersible tablets) versus the current risdiplam oral solution formulation in healthy male and female participants. The effect of food on these two dispersible tablets and the current oral solution will be studied, as well as the effect of omeprazole on the dispersible tablets.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT04718181 BP42066
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 55 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- A body mass index (BMI) of 18.0 to 32.0 kg/m2
- Male participants, whose partners are women of childbearing potential (WOCBP) or pregnant, must remain abstinent or use adequate contraception methods (both male participant and non-pregnant WOCBP partner) during the treatment period and until 4 months after the last dose of risdiplam or for

pregnant female partners during the treatment period and until 28 days after the last dose of risdiplam. Males must refrain from donating sperm during the treatment period and until 4 months after the last dose of risdiplam.
- Willingness and ability to complete all aspects of the study
- A female subject is eligible to participate if she is a woman of non-childbearing potential (WONCBP)

Exclusion Criteria:

- History of any clinically significant gastrointestinal (GI), renal, hepatic, broncho-pulmonary, neurological, psychiatric, cardiovascular, endocrinological, hematological, or allergic disease, metabolic disorder, cancer or cirrhosis
- Concomitant disease or condition that could interfere with, or treatment of which might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the participant in this study, including but not limited to the following: Any major illness within 1 month before screening or any febrile illness within 1 week prior to screening and up to first study drug administration
- History or evidence of any medical condition potentially altering the absorption, metabolism, or elimination of drugs
- Surgical history of the GI tract affecting gastric motility or altering the GI tract (with the exception of uncomplicated appendectomy and hernia repair; a cholecystectomy is exclusionary)
- History or presence of clinically significant ECG abnormalities (at Screening only) or cardiovascular disease (e.g., cardiac insufficiency, coronary artery disease, cardiomyopathy, congestive heart failure, family history of congenital long QT syndrome, family history of sudden death)
- History of malignancy in the past 5 years
- Confirmed systolic blood pressure (BP) >140 or <90 mmHg, and diastolic BP >90 or <50 mmHg at Screening only
- Confirmed resting heart rate >100 or <40 beats per minute (bpm) at Screening only
- Clinically significant abnormalities in laboratory test results including hematology, chemistry panel, and urinalysis
- Positive result on human immunodeficiency virus (HIV)-1, HIV-2, hepatitis B virus, or hepatitis C virus (serology) tests at Screening only
- Any suspicion or history of alcohol abuse and/or any history or suspicion of regular consumption/ addiction of drugs of abuse within 2 years prior to study drug administration or a positive drug screen test as performed at Screening
- Any consumption of tobacco- or nicotine-containing products from 1 month before Check-in until the end of the study
- Donation of blood or blood products for transfusion over 500 mL within 3 months prior to first study drug administration and for the duration of the study
- Currently enrolled in a clinical study involving another investigational product or in any other type of medical research, or have received the last dose of another investigational product within the last 90 days from clinic check-in (Day -1).
- Use of any prescription (other than hormone replacement therapy) or over-the-counter medications, including herbals and vitamins, within 30 days prior to Check-in
- Any clinically significant history of hypersensitivity or allergic reactions, either spontaneous or following study drug administration, or exposure to food or environmental agents
- History of hypersensitivity to any of the excipients in the formulation of the study drug
- Participants under judicial supervision, guardianship, or curatorship