ForPatients
by Roche

Angelman Syndrome

A Study To Assess Distribution Of RO7248824 In The Central Nervous System Following Single Intrathecal Doses Of [89zr] Labeled RO7248824 In Healthy Male Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04863794 BP41660

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 Non-Randomized, Open-Label, Adaptive, Single Center, Positron Emission Tomography (Pet) Study To Assess Distribution Of RO7248824 In The Central Nervous System Following Single Intrathecal Doses Of [89zr] Labeled RO7248824 In Healthy Male Participants

Trial Summary:

The aim of Study BP41660 is to quantify the amount and concentration of [89Zr]DFO-RO7248824 in the brain with positron emission tomography (PET) following a single sub-pharmacological dose of RO7248824 and [89Zr]DFO-RO7248824 administered via IT injection to healthy participants.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT04863794 BP41660
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#25 Years & # 55 Years	Accepts Healthy Volunteers

Inclusion Criteria:

Informed Consent

- Able and willing to provide written informed consent and to comply with the study protocol according to ICH and local regulations

Age

- Aged from 25 to to 55 years at the time of dosing

Type of Participants and Disease Characteristics

- Overtly healthy (defined by absence of evidence of any active or chronic disease) as determined by medical evaluation including:
- A detailed medical and surgical history * A complete physical and neurological examination * Vital signs * 12-lead ECG * Hematology * Coagulation * Blood chemistry * Serology and urinalysis
- Fluent in the language of the Investigator and study staff, and able to communicate with the study staff

Weight

- Body mass index (BMI) of # 18 to # 30 kg/m2 at screening

Sex

- Male participants only who, for 3 months after the dosing of RO7248824, agree to:
- Remain abstinent (refrain from heterosexual intercourse) or use contraceptive barrier measures such as a condom, with a female partner of childbearing potential, or pregnant female partner, to avoid exposing the embryo * Refrain from donating sperm

Exclusion Criteria:

Medical Conditions

- Any condition or disease detected during the medical interview/physical examination that would render the participant unsuitable for the study, place the participant at undue risk or interfere with the ability of the participant to complete the study, as determined by the Investigator
- History or presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, hematological, or neurological disorders capable of significantly altering the absorption, metabolism, or elimination of drugs; constituting a risk when taking the study treatment; or interfering with the interpretation of data
- History or presence of clinically significant cardiovascular disease in the opinion of the Investigator
- History or presence of an abnormal ECG that is clinically significant in the Investigator's opinion
- Uncontrolled arrhythmias or history of clinically significant arrhythmias
- Confirmed abnormal blood pressure
- Abnormal pulse rate
- Abnormalities in brain and
- Evidence or history of clinically significant back pain, back pathology and/or back injury
- Evidence or history of significant active bleeding or coagulation disorder
- Allergy to lidocaine (Xylocaine) or its derivatives
- Medical or surgical conditions for which LP or associated procedures is contraindicated
- Alanine transaminase (ALT) and bilirubin > 1.5 x upper limit of normal (ULN)
- Current or chronic history of liver disease, or known hepatic or biliary abnormalities
- History of convulsions or history of loss of consciousness
- Sensitivity to any of the study treatments, or components thereof, or drug or other allergy that, in the opinion of the Investigator, contraindicates the participation in the study

- Any major illness within one month before the screening examination or any febrile illness within one week prior to screening and up to first study drug administration
- Clinically significant abnormalities in laboratory test results

Prior/Concomitant Therapy

- Used or intends to use any prohibited medications
- Likely to need concomitant medication during the study period

Prior/Concurrent Clinical Study Experience

- Participating in an investigational drug or device study within 60 days prior to screening, as calculated from the day of follow-up from the previous study, or more than 4 participations in an investigational drug or device study within a year prior to dosing
- Previously (within the past 12 months from dosing) included in medical research and/or a medical protocol involving PET or radiological investigations, or other exposure to ionizing radiation, which combined with this study would result in an effective dose of 10 mSv or more

Diagnostic Assessments

- Positive test for drugs of abuse or alcohol
- Presence of hepatitis B surface antigen (HBsAg), positive hepatitis C antibody test result at screening or within 3 months prior to first dose of study treatment)
- Evidence of HIV infection and/or positive human HIV antibodies

Other Exclusions

- Any suspicion or history of alcohol abuse and/or suspicion of regular consumption of drug of abuse or previous history of or treatment for a dependence disorder
- Regularly smoking more than 5 cigarettes daily or equivalent and unable or unwilling not to smoke or not to use other nicotine containing products during the in-house period
- Donated over 500 mL of blood or blood products or had significant blood loss within 3 months prior to screening
- Under judicial supervision, guardianship or curatorship
- Not able to undergo PET, CT, or MRI scans
- Previous lumbar surgery that is likely, in the opinion of the Investigator or surgical team, to make IT injection unduly difficult or hazardous
- Scoliosis or spinal deformity preventing IT injection