ForPatients
by Roche

Esclerose múltipla recidivante (EMR)

Um estudo para avaliar como o fenebrutinib é processado pelo corpo, o seu efeito na prevenção de sinais de esclerose múltipla recidivante e a sua segurança em crianças e adolescentes com esclerose múltipla recidivante

A Pharmacokinetics (PK), Pharmacodynamics (PD), Safety and Tolerability Study of Fenebrutinib in Children and Adolescents With Relapsing Multiple Sclerosis (RMS)

Trial Status	Trial Runs In	Trial Identifier
Recrutando	3 Countries	NCT07161258 2024-519800-28-00 CN45847

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

An Open-label, Single-arm Study to Evaluate Pharmacokinetics, Pharmacodynamic Effects, Safety and Tolerability of Fenebrutinib in Children and Adolescents With Relapsing Multiple Sclerosis

Trial Summary:

This open label, single arm study will evaluate the PK and PD effects of fenebrutinib in children and adolescents with RMS aged between 10 and < 18 years. This study consists of a Dose Exploration Period and an Optional Extension Period. Eligible participants may choose to continue treatment with fenebrutinib in the optional extension period after completing the dose exploration period.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT07161258 2024-519800-28-00 CN45847
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#10 Years & # 17 Years	No

Inclusion Criteria:

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- A diagnosis of RMS in accordance with the International Pediatric Multiple Sclerosis Study Group (IPMSSG) criteria for pediatric MS, Version 2012, and the revised 2017 McDonald Criteria and one or more of the following: at least one MS relapse during the previous year or two MS relapses in the previous 2 years or evidence of at least one Gd enhancing lesion on MRI within 6 month
- Expanded Disability Status Scale (EDSS) at screening from 0 to 5.5 points, inclusive
- Children and adolescents must have received all childhood vaccinations as per local/national recommendations for childhood vaccination against infectious diseases

Exclusion Criteria:

- A diagnosis of primary progressive multiple sclerosis (PPMS) or non-active secondary progressive multiple sclerosis (SPMS)
- Co-morbid Conditions:
- Potentially confounding neurological, somatic, or metabolic disorders
- Current clinically significant psychiatric or medical illness
- History of cancer, transplants, or bleeding disorders
- Inability to complete an MRI scan or get gadolinium
- Abnormal liver function tests or blood counts
- Peripheral venous access that precludes venous blood sampling as required per study protocol
- Sensitivity or intolerance to any ingredient (including excipients) of fenebrutinib tablets
- Active, recurrent, or chronic infections
- Recent or anticipated use of prohibited medications/treatments:
- Certain disease-modifying therapy (DMT) and other immunosuppressants
- Drugs interacting with fenebrutinib (Cytochrome P450 3A4 [CYP3A4] inhibitors)
- Any other investigational therapy, anticoagulants, certain vaccines

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