ForPatients
by Roche

Non Alcoholic Steato-HepatitisChronic Kidney Disease

A study of a new medicine (fazpilodemab) in people with a type of liver disease called non-alcoholic steatohepatitis or NASH

A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of BFKB8488A Compared With Placebo in Participants With Non-Alcoholic Steatohepatitis

Trial Status	Trial Runs In	Trial Identifier
Terminated	5 Countries	NCT04171765 GC41033

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase II, Randomized, Parallel-Group, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of BFKB8488A Compared With Placebo in Patients With Non-Alcoholic Steatohepatitis

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of BFKB8488A compared to placebo in participants with non-alcoholic steatohepatitis (NASH).

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 2
Sponsor	Phase

NCT04171765 GC41033
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

Inclusion Criteria:

- Confirmed diagnosis of NASH as documented through liver biopsy performed no more than 6 months before randomization, defined according to NASH CRN criteria along with a NASH CRN fibrosis score between F2 and F3

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- Hepatic steatosis on MRI (>= 8% average PDFF) prior to randomization

Exclusion Criteria:

- History of any liver disease other than NASH, except for resolved, self-limited illnesses such as Hepatitis A or E, and previous Hepatitis C
- Weight gain > 10% or loss > 5% within 3 months prior to randomization
- History of liver transplantation
- Current or history of significant alcohol consumption

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