ForPatients
by Roche

Renal FailureChronic Kidney Disease

A Study Investigating the Safety of RO7795081 and How the Body Processes RO7795081 in People With Normal or Decreased Kidney Functions

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07741604 BP46039

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 Two-part, Non-randomized, Open-label, Parallel-group Study to Assess the Effect of Renal Impairment on the Pharmacokinetics and Safety of RO7795081 Following a Single Oral Dose of RO7795081

Trial Summary:

The purpose of this study is to assess the effect of renal impairment on the pharmacokinetics (PK) and safety of RO7795081, following a single oral dose in participants with renal impairment compared with participants with normal renal function. In Part 1, participants with normal renal function and participants with severe renal impairment or kidney failure not receiving dialysis will receive RO7795081. Part 2 is optional and will be conducted based on the results of Part 1. If Part 2 is implemented, additional participants with normal renal function and participants with mild or moderate renal impairment may be enrolled to receive RO7795081.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT07741604 BP46039
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 85 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Ability and willingness to comply with all aspects of the protocol including completion of assessments for the duration of the study
- Estimated Glomerular Filtration Rate (eGFR) calculated using the Body Surface Area (BSA)-adjusted Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation
- Participants with mild, moderate, or severe renal impairment/kidney failure and stable renal function
- Participants with normal renal function matched to participants with renal impairment

Exclusion Criteria:

- 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 in the opinion of the Investigator
- History or evidence of any medical condition other than renal impairment capable of significantly altering the absorption, metabolism, or elimination of drugs
- Surgical history of the gastrointestinal (GI) tract affecting gastric motility or altering the GI tract (with the exception of uncomplicated appendectomy and cholecystectomy)
- History of malignancy in the past 5 years, except for fully treated local basal carcinoma, or fully treated carcinoma in situ of cervix
- Personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2
- History of cardiovascular, neurologic, psychiatric, or infectious disease
- History of hypersensitivity to any of the excipients in Glucagon-like Peptide-1 (GLP-1) agonists
- Bipolar disorder, schizophrenia, or any other serious psychiatric condition
- Type 1 diabetes or poorly controlled Type 2 diabetes
- Current or recent participation in another clinical study
- Pregnancy or breastfeeding
- Positive Human Immunodeficiency Virus (HIV), hepatitis B, hepatitis C, or tuberculosis test
- History of alcohol or substance abuse