

A Double-blind, Randomized Controlled Trial to Investigate the Efficacy, Safety, and Pharmacokinetics of Pegloticase Administration Via Subcutaneous and Intravenous Routes Both With Methotrexate in Participants With Uncontrolled Gout

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria * Participant has provided informed consent before initiation of any trial-specific activities/procedures. * Age $\geq$ 18 years or $\geq$ legal age within the country if it is older than 18 years. * Participants willing and able to comply with the prescribed treatment protocol and evaluations for the duration of the trial. * Participants with uncontrolled gout, as meeting the protocol defined criteria. Exclusion Criteria * Glucose-6-phosphate dehydrogenase deficiency (tested at the screening visit). * Liver transaminase levels (aspartate aminotransferase [AST] or alanine aminotransferase [ALT]) > 1.25 x upper limit of normal (ULN) or albumin $<$ the lower limit of normal (LLN) at the screening visit. * Uncontrolled diabetes mellitus and/or hemoglobin A1c (HbA1c) $> 8\%$. * Known intolerance to MTX. * Participant received prior treatment with pegloticase, another recombinant uricase (ie, rasburicase or pegadricase), or concomitant therapy with a polyethylene glycol (PEG)-conjugated drug. * A known intolerance to all protocol standard gout flare prophylaxis regimens (ie, participant must be able to tolerate at least 1 of the following: colchicine and/or non-steroidal anti-inflammatory drug and/or low-dose prednisone ≤ 10 mg/day or equivalent dose of other corticosteroid). * Chronic renal impairment defined as estimated glomerular filtration rate (eGFR) based on Modification of Diet in Renal Disease (MDRD) calculations < 40 mL/min/1.73 m² or currently on dialysis.

Conditions & Interventions

Interventions:

DRUG: Pegloticase, DRUG: Methotrexate

Conditions:

Uncontrolled Gout

Keywords:

Uncontrolled Gout, Pegloticase, KRYSTEXXA, Kadence

More Information

Contact(s): Amgen Call Center - medinfo@amgen.com

Principal Investigator:

IRB

Number:

System ID: NCT07388498

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