

# A First-in-human Study of KK8123 in Adults With X-linked Hypophosphatemia

NCT06525636

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Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Kyowa Kirin Co., Ltd.
Enrollment	24 participants

## Key Eligibility Criteria

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### Inclusion (22)

- Male or female patients aged 18 to 65 years inclusive at the time of signing the ICF.
- Body weight is at least 40 kg.
- Diagnosed with XLH (as documented by the investigator).
- Have a value of fasting serum phosphorus  $\leq$  2.5 mg/dL (0.81 mmol/L) at Screening.
- Have a value of renal TmP/GFR  $\leq$  2.5 mg/dL (0.81 mmol/L) at Screening.

... and 17 more (see full listing online)

### Exclusion (36)

- For XLH patients previously treated with burosumab, use of burosumab within 7 months prior to ICF signature.
- Prior history of positive test for human immunodeficiency virus antibody, positive test for hepatitis B surface antigen, and/or hepatitis C virus antibody at Screening.
- History of hypersensitivity to any ingredient of any therapeutic monoclonal antibody.
- Have an active infection.
- Grade 3 or greater nephrocalcinosis as confirmed by renal ultrasound.

... and 31 more (see full listing online)

## Locations (9 total)

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University of California - San Francisco, San Francisco, California, United States  
Yale Center for XLH/ Yale University School of Medicine, New Haven, Connecticut, United States  
Indiana University School of Medicine University Hospital, Indianapolis, Indiana, United States  
... and 6 more locations

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<https://clinicaltrials.gov/study/NCT06525636>

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