

# Study of Bitopertin in Participants With EPP or XLP (APOLLO)

NCT06910358

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Status	RECRUITING
Phase	Phase 3
Sponsor	Disc Medicine, Inc
Enrollment	150 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Aged 12 years or older at the time of study consent.
  - Diagnosis of EPP or XLP, based on medical history by ferrochelatase (FECH) or aminolevulinic acid synthase 2 (ALAS2) genotyping or by biochemical porphyrin analysis.
  - Minimum daily Sun Exposure Diary compliance e85% on Days -14 through Day -1, inclusive, during screening, and at least 1 successfully completed Sun Exposure Challenge (adults only, as this assessment is optional for adolescents) or historical recall of time to prodrome
  - Body weight e32 kg (ages 12 to <18 years), body mass index e18.5 kg/m2 (ages e18 years) at screening.
  - Washout of at least 2 months prior to screening of afamelanotide and dersimelagon, if applicable.
- ... and 2 more (see full listing online)

### Exclusion (20)

- Major surgery within 8 weeks before screening or incomplete recovery from any previous surgery.
  - Other than EPP or XLP, an inherited intrinsic or extrinsic red cell disease associated with anemia.
  - Known hypersensitivity to any component of the study drug.
  - History of liver transplantation or anticipated need for liver transplantation.
  - History of alcohol dependence or excessive alcohol consumption, as assessed by the Investigator.
- ... and 15 more (see full listing online)

## Locations (28 total)

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Marvel Clinical Research, Huntington Beach, California, United States  
University of California San Francisco, San Francisco, California, United States  
University of Miami Miller School of Medicine, Miami, Florida, United States  
... and 25 more locations

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<https://clinicaltrials.gov/study/NCT06910358>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).