

A Study of Dotinurad Versus Allopurinol in Participants With Gout

NCT07089875

Status	RECRUITING
Phase	Phase 3
Sponsor	Crystalys Therapeutics
Enrollment	500 participants

Key Eligibility Criteria

Inclusion (7)

- Between 18 and 75 years of age (inclusive) at the time of signing informed consent.
- Diagnosis of gout based on 2015 American College of Rheumatology (ACR)-European Union League Against Rheumatism (EULAR) criteria for at least 1 year.
- Had at least 2 gout flares in the 12 months prior to Screening (reported by the participant or documented in the participant's medical records).
- Participant must be on a stable background allopurinol dose of e300 mg/day (200 mg/day for those with moderate renal impairment) up to 600 mg/day for at least 3 months prior to Screening and remain on their dosing regimen until Day 1.
- sUA level e6.5 mg/dL at Screening Visit 1 (Day -35 Visit) and Screening Visit 2 (Day -7 Visit).

... and 2 more (see full listing online)

Exclusion (6)

- History of or presence of kidney stones within 1 year prior to Screening.
- History of or presence of malignancy in the last 5 years other than treated cutaneous basal or squamous cell carcinoma.
- Hypersensitivity or intolerance to dotinurad or to colchicine and nonsteroidal anti-inflammatory drugs.
- Known or suspected history of drug abuse, a positive drug test at Screening Visit 1, or a recent history of alcohol abuse.
- Known history of or positive results for human immunodeficiency virus, Hepatitis B Surface Antigen, or Hepatitis C antibodies during Screening.

... and 1 more (see full listing online)

Locations (95 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
Alabama Clinical Therapeutics, Birmingham, Alabama, United States
Arizona Arthritis & Rheumatology Associates (AARA) - Gilbert, Gilbert, Arizona, United States
... and 92 more locations

<https://clinicaltrials.gov/study/NCT07089875>

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