Tigulixostat (IBI128) vs Febuxostat in Gout

NCT07414394

Status	RECRUITING
Phase	Phase 3
Sponsor	Innovent Biologics Technology Limited (Shanghai R&D Center)
Enrollment	600 participants

Key Eligibility Criteria

Inclusion (8)

- Participants must meet all of the following criteria to be eligible for the study:
- Age e 18 years, male or female.
- Body mass index (BMI) between 18 and 40 kg/m².
- Diagnosed with gout according to the 2015 ACR/EULAR classification criteria.
- Serum uric acid (sUA) at screening:

... and 3 more (see full listing online)

Exclusion (27)

- Participants who meet any of the following criteria will be excluded from the study:
- History of allergy or intolerance to any component of febuxostat or Tigulixostat, or previous evidence of poor response to febuxostat treatment (e.g., sUA \> 420 μmol/L after e 6 weeks of febuxostat e 40 mg).
- Acute gout attack within 4 weeks prior to screening or from screening to first dose.
- Use of uric acid-lowering drugs (e.g., allopurinol, febuxostat, probenecid, benzbromarone, dotinurad, recombinant uricase; excluding sodium bicarbonate) within 2 weeks before screening.
- Hyperuricemia caused by secondary gout (e.g., myeloproliferative disease, tumor, organ transplantation, enzyme deficiency, renal tubular dysfunction, lead poisoning, psoriasis, medications), excluding hyperuricemia due to renal insufficiency.

... and 22 more (see full listing online)

Locations (1 total)

Shanghai Fudan University HuaShan Hospital, Shanghai, Shanghai Municipality, China