Clinical Exploration Study of YOLT-203 in the Treatment of Type 1 Primary Hyperoxaluria (PH1)

NCT06511349

Status	RECRUITING
Phase	Early Phase 1
Sponsor	RenJi Hospital
Enrollment	21 participants

Key Eligibility Criteria

Inclusion (5)

- The age is e 2 years old at the time of signing the informed consent.
- Have AGXT gene mutations and be diagnosed with primary hyperoxaluria (PH1); eGFR e 30 ml/min/1.73m2.
- At least 2 times of 24-hour urinary oxalate excretion e 0.7 mmol/1.73m2/day or the ratio of urinary oxalate to creatinine in a single urine collection must be higher than the upper limit of normal (ULN) for the corresponding age.
- If treated with vitamin B6, the treatment has been stable for 90 days before enrollment in the study and is willing to maintain the stable treatment plan unchanged during the study.
- The patient himself/herself or the guardian voluntarily signs the informed consent.

Exclusion (16)

- The investigator judges that there is clinical evidence of systemic extra-renal oxalate deposition.
- Have any of the following laboratory parameter assessment results at screening:
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) \> 2 x the upper limit of normal (ULN).
- Total bilirubin \> 1.5 x ULN. If the increase in total bilirubin is caused by diagnosed Gilbert's syndrome and the total bilirubin \< 2 x ULN, it is eligible.
- International normalized ratio (INR) \> 1.5 (Patients on oral anticoagulants \[such as warfarin\] and with INR \< 3.5 will be allowed to participate).

... and 11 more (see full listing online)

Locations (1 total)

Deparment of Liver Surgery, Ren Ji Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, Shanghai Municipality, China