Background

Enteric hyperoxaluria (EH) is a serious and debilitating disease that affects approximately 150,000 people in the United States. Patients with EH, characterized by excessive oxalate absorption linked to malabsorption (e.g., bariatric surgery, short-bowel syndrome), experience high oxalate absorption, early onset of typical urinary tract stones, and elimination of calcium oxalate. The associated risk of chronic kidney disease (CKD) is well characterized. Resection of the gut is the only effective treatment for EH.

Methods

Pilot Study of Reloxaliase in Patients with Severe Enteric Hyperoxaluria and Hyperoxalemia: A Preclinical Analysis of Study ALLN-177-206

This study enrolled patients with severe EH with CKD and hyperoxalemia (elevated POx) and also patients with primary enteric hyperoxaluria. The study aimed to evaluate the effects of reloxaliase on plasma oxalate (POx) and urinary oxalate (UOx) levels.

Results

Subjects received 7,500 units of reloxaliase 5x/day with meals and snacks. The mean reduction from baseline of POx was 38.5% (range –16% to –68%) in all subjects (n=9). The majority of subjects were male (n=6; 67%), 5 were on dialysis, and 3 had previously received a kidney transplant (n=3).

Safety

The most common adverse events (AEs) were gastrointestinal (GI) events associated with malabsorption (e.g., bariatric surgery, short-bowel syndrome) such as abdominal distention (n=4), flatulence (n=7), and abdominal pain (n=5). Gastrointestinal events were manageable with dose reductions or discontinuation of study drug.

Conclusions

Reloxaliase substantially reduced measures of oxalate burden in patients with EH and advanced CKD. The study results support a Phase 2 clinical trial to evaluate reloxaliase in patients with EH.

Acknowledgments

We want to thank all patients and families for participating. This study is ongoing and please contact us if you are interested in taking part in the study.

References


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