

Decentralized Clinical Research Trial for Patients with Primary Distal Renal Tubular Acidosis (dRTA)

ARENA2 Phase 3 Study – USA and Canada

- Actively recruiting patients with inherited dRTA
- 12-week duration, randomized withdrawal design
- Virtual study design – allowing for study participation without hospitalization

Pivotal Study Objective

Compare the efficacy of ADV7103 versus placebo in preventing metabolic acidosis, defined as 2 consecutive serum bicarbonate levels < 18 mEq/L for subjects ≥ 4 years old and < 17 mEq/L for subjects < 4 years old, during the Withdrawal Period.

Long-term Extension Study

Patients completing Phase 3 have long-term access to ADV7103

About ADV7103

ADV7103 is an innovative prolonged-release oral granule combining the advantages of potassium citrate and potassium bicarbonate designed to improve treatment effectiveness with twice daily dosing.



Inclusion criteria

- Female or male patients ≥ 6 months of age and ≤ 65 years
- A previous diagnosis of primary dRTA based on documented history of non-anion gap, hypokalemic, hyperchloremic metabolic acidosis
- Requiring ≥ 0.9 mEq/kg/day of alkali therapy to maintain serum bicarbonate levels

Exclusion criteria

- Acquired /Secondary dRTA
- eGFR <60 mL/min/1.73m²
- Patient has evidence of proximal tubule dysfunction
- Patients requiring contraindicated medication

Principal Investigator: Larry Greenbaum, MD, PhD
[ClinicalTrials.gov Identifier NCT03644706](https://clinicaltrials.gov/ct2/show/study/NCT03644706)

Results of European Phase 3 Trial Comparing ADV7103 to Standard of Care

Efficacy and safety of an innovative prolonged-release combination drug in patients with distal renal tubular acidosis (dRTA): an open-label comparative trial versus standard of care (SoC) treatments



HYPOTHESIS: Metabolic control in patients with dRTA is improved with ADV7103 when compared vs. SoC treatments

DESIGN & OUTCOMES:

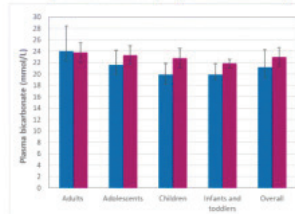
SoC (N=37)

ADV7103 (N=34)

Switch from SoC to ADV7103



Pediatric and adult patients with dRTA



- ▲ Plasma bicarbonate levels (superiority p = 0,0008)
- ▲ Bicarbonate in normal range (McNemar's p < 0,001)
- ▲ Plasma potassium levels
- ▲ Risk of stone formation (McNemar's p = 0,021)
- ▲ Palatability (d = 25 mm in VAS)
- ▲ Number of daily intakes
- ▲ GI tolerability problems (d = -14,2 mm in VAS)

CONCLUSION: When switching from SoC to ADV7103, management of plasma bicarbonate levels and risk of stone formation, as well as palatability and gastrointestinal safety, were significantly improved

Bertholet-Thomas et al.

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If you are interested to learn more about the ARENA2 trial or have a patient that is interested to participate contact:

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