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IRB Approved at the
Protocol Level
Apr 19, 2021

ARENA2

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
- COVID-friendly virtual design option allows patients to complete the study from the comfort of their home

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 ≥4 years old and < 17 mEq/L for subjects < 4 years old during the Withdrawal Period.

Long-term Extension Study

Patients completing the Phase 3 study have access to ADV7103 in the Extension Study

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

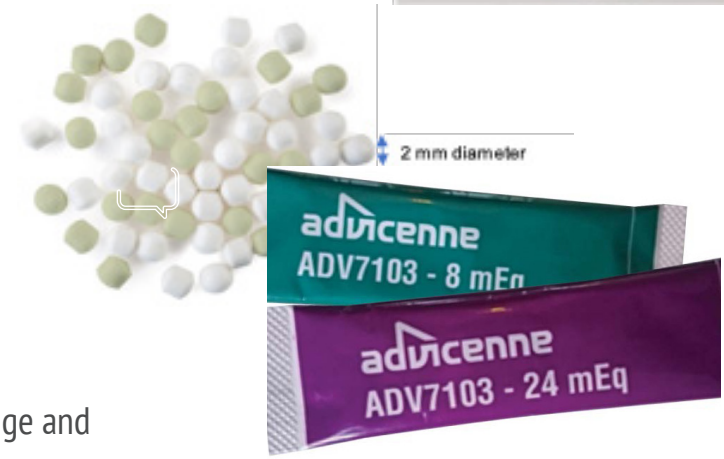
Exclusion criteria

- Acquired /Secondary dRTA
- eGFR <60 mL/min/1.73m^2
- Patient has evidence of proximal tubule dysfunction
- Patients requiring contraindicated medication

ClinicalTrials.gov Identifier NCT03644706

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.



Patient Navigation Services

- Assists patients with customized navigation plan to suit individual needs
- Offers ongoing, patient-centered psycho-educational support for patients and families regarding trial-related issues
- Maintains weekly check-ins with patients and families to ensure patients feel supported and engaged

TO LEARN IF THE ARENA2 CLINICAL TRIAL IS RIGHT FOR YOU, TALK TO YOUR DOCTOR OR EMAIL ARENA2INFO@ADVICENNE.COM