

<u>A</u>ldosterone blo<u>C</u>kade for <u>H</u>ealth<u>I</u>mprovement <u>EV</u>aluation in <u>E</u>nd-stage renal disease





Background and Study Rationale

- Globally approximately 2.5 million people receive dialysis for kidney failure
- The outcomes for many patients receiving dialysis are poor with a median survival of only 3 years, frequent hospitalizations, and poor health related quality of life
- Heart disease is the leading cause of death for patients that require dialysis but there no treatments that are known to effectively reduce heart related deaths and hospitalizations





Importance of the ACHIEVE Study

- Aldosterone is a hormone that may play an important role in causing heart disease
- Blocking the actions of aldosterone reduce heart related deaths and hospitalizations in patients with normal kidney function and look promising for patients who have kidney failure treated with dialysis
- The ACHIEVE trial will help establish whether blocking aldosterone with a widely available drug called spironolactone prevents heart related deaths and hospitalizations in patients that receive dialysis





Eligibility Assessment

Inclusion Criteria

Exclusion Criteria

- 1. Age
 - a) ≥45 years
 - <u>or</u>
 - b) ≥18 with a history of diabetes
- 2. On dialysis \geq 90 days
- 3. On either
 - a) Hemodialysis at \geq 2 tx/week
 - <u>or</u>
 - b) Peritoneal dialysis ≥ 1 exchange/day
- 4. Provides informed consent

- Hyperkalemia

 a) Serum potassium >5.8 mmol/L in 6 weeks
 - prior
 - <u>or</u>
 - b) Serum potassium >6.0 mmol/L during active run-in
- 2. Currently taking & unable to withdraw MRA
- 3. Known sensitivity or allergy to spironolactone
- 4. Current or planned pregnancy or breastfeeding
 - 5. Scheduled living related donor renal transplant
 - 6. Life expectancy < 6 months in the opinion of a treating nephrologist
 - Enrolled in another interventional trial testing a MRA or drug that has a known/likely interaction with spironolactone

Study Flow Diagram





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