

## AREN2231; Risk Adapted Treatment of Unilateral Favorable Histology Wilms Tumors (FHWT)

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** Not specified

This study is NOT accepting healthy volunteers

**Inclusion Criteria:**

- Age: Patients must be more than 30 years old - Diagnosis: Patients with newly diagnosed Stage I-IV
- Favorable Histology Wilms Tumor confirmed by central review and with a qualifying Initial Stratum Assignment received on APEC14B1-REN

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**Exclusion Criteria:**

- Patient with a diagnosis of Stage V Bilateral Wilms Tumor - Patients who in the opinion of the investigator are not able to comply with the study procedures are not eligible -Patients with any uncontrolled, intercurrent illness including but not limited to symptomatic congestive heart failure - Patients with Stage I FHWT with a known or suspected Wilms Tumor predisposition syndrome or condition (contralateral nephrogenic rests and/or unilateral multicentric tumors) are excluded from treatment on the mVLR (Nephrectomy Only) arm

### Conditions & Interventions

**Conditions:**

Cancer, Cancer, Kidney, Prostate & Urinary

**Keywords:**

Wilms Tumors

### More Information

**Description:** This study aims to improve the outcomes within cohorts of favorable-histology Wilms tumor (FHWT) patients, and maintain those outcomes despite therapy reduction. In this case, an improved outcome would be considered an improvement in event-free survival rates (EFS). Patients will be stratified to different treatment groups based upon age, response to treatment, and other factors. This trial will include six chemotherapy treatment regimens, and there will also be expansion and refinement of the cohort of patients who are treated with nephrectomy only. Exploratory aims will address aspects such as radiology, surgery, radiation oncology, pathology, and the biological aspects of FHWT.

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**Phase:** PHASE3

**IRB Number:** STUDY00025902

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