# A Study Using Risk Factors to Determine Treatment for Children With Favorable Histology Wilms Tumors (FHWT)

**Status:** RECRUITING

## Eligibility Criteria

**Age:** Up to 30 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

**Inclusion Criteria:**

* Patients must be enrolled on APEC14B1 and consent to Part A

•Eligibility Screening prior to enrollment on AREN2231. * Patients must be \< 30 years old at enrollment. * Patients with newly diagnosed Stage I-IV Favorable Histology Wilms Tumor confirmed by central review and with a qualifying Initial Stratum Assignment on APEC14B1. * Patients must receive a qualifying Initial Stratum Assignment on APEC14B1-REN by Day 14 post-diagnostic procedure (nephrectomy or biopsy), where that procedure is Day 0. * Patients must enroll on AREN2231 by Day 14. * Exceptions: If patient reaches Day 14 (post initial diagnostic nephrectomy or biopsy) without receiving an Initial Stratum Assignment on APEC14B1-REN, patient will not be eligible for enrollment on AREN2231 unless all required materials (reports and Case Report Forms and specimens) for an Initial Stratum Assignment arrived by Day 7, but an Initial Stratum Assignment was not completed by Day 14. In these circumstances, after obtaining appropriate protocol consent, the patient may proceed with treatment according to local institutional staging and enroll within 5 calendar days of notification of the central Initial Stratum Assignment being issued, only if the AREN2231 Initial Stratum Assignment is in agreement with any treatment already initiated. If the Initial Stratum Assignment is not in agreement with the local institution's assessment then the patient will be ineligible for AREN2231. * All sites must have sent or plan to send diagnostic tumor sample for molecular testing through a Clinical Laboratory Improvement Act (CLIA)-certified (or equivalent if outside of the United States \[US\]) laboratory that can detect Loss of Heterozygosity (LOH) of chromosome 1p AND 16q, and gain of chromosome 1q. Patients potentially eligible for mVLR must also have LOH of chromosome 11p15 included. * Note: Patients are eligible for enrollment prior to obtaining these molecular testing results, and it is strongly recommended that patients are enrolled before these results are available. However, molecular results must be returned and uploaded to APEC14B1-REN for integration into risk stratification by the required timepoints (specific timelines vary by treatment arm). Patients who do not have molecular results available by the arm-specific timepoints may be taken off protocol therapy. * Patients who have an upfront nephrectomy must have at least one lymph node sampled and confirmed as a lymph node by central pathology review to be eligible. * Note: Lymph node sampling will also be required at delayed nephrectomy. Patients who do not have a lymph node sampled and confirmed as a lymph node by central pathology review at delayed nephrectomy will be taken off protocol therapy. * Karnofsky performance status must be ≥ 50 for patients \> 16 years of age and the Lansky performance status must be ≥ 50 for patients ≤ 16 years of age. * Serum total bilirubin ≤ 1.5 X upper limit of normal (ULN) OR direct bilirubin ≤ 3X ULN for subjects with total bilirubin levels \> 1.5 ULN (within 7 days prior to enrollment). * Aspartate aminotransferase (AST/serum glutamate oxaloacetic transaminase \[SGOT\]) OR alanine transaminase (ALT/serum glutamic pyruvate transaminase \[SGPT\]) ≤ 3X ULN OR ≤ 5 X ULN for patients with liver metastases (within 7 days prior to enrollment). * Shortening fraction of ≥ 27% by echocardiogram, or ejection fraction of ≥ 50% (within 7 days prior to enrollment) * Note: This criteria only applies to patients centrally classified as Stage IV. Stage II and III patients subsequently assigned to a doxorubicin arm will be off protocol therapy if they do not meet this criteria at time of cardiac function assessment. * Known HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. * All patients and/or their parents or legal guardians must sign a written informed consent. * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met.

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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. * Notes: * In the context of the renal tumor protocols, multicentric tumors and multifocal tumors are equivalent terms, and refer to the occurrence of two or more tumors arising within one kidney. * Exclusion from the Nephrectomy Only arm applies to two groups of patients: * Patients \< 4 years with Stage I FHWT other than epithelial subtype AND * Stage I patients of any age with Epithelial WT * For the purpose of exclusion from the Nephrectomy Only Arm, known or suspected WT predisposition syndromes or conditions are defined as follows: * WT Predisposition Syndromes: Beckwith Wiedemann Spectrum, Denys Drash, Trisomy 18, Idiopathic Hemihypertrophy/Isolated Lateralized Overgrowth, WAGR, Simpson-Golabi-Behmel, Bohring-Opitz, or other conditions considered by treating physician to predispose to WT. * WT Predisposing Conditions: * A unilateral WT and (radiologic or pathologic) determination of contralateral nephrogenic rest(s) AND/OR * Unilateral multicentric WT * Patients treated with partial nephrectomy at initial diagnosis are excluded from mVLR (Nephrectomy Only) arm. * Patients with lung metastases as the only metastatic site who already had complete resection of all radiologically evident lung nodules, and have at least one nodule confirmed pathologically as tumor. * Please note: Those with lung metastases as the only metastatic site who have complete resection of all radiologically evident lung nodules after enrollment but prior to the lung imaging following Cycle 2 of DD-4A will be inevaluable for lung assessment and subsequent stratum assignment and will, therefore, come off protocol therapy. * Patients with known Charcot-Marie-Tooth syndrome. * Patients who have had prior tumor-directed chemotherapy or radiotherapy for the current diagnosis except for therapy delivered for an emergent issue, as medically indicated. * Patients who will potentially require doxorubicin on this study and have previously received doxorubicin for another diagnosis. * Patients receiving concurrent chemotherapy for a different diagnosis. * Female patients who are pregnant since fetal toxicities and teratogenic effects have been noted for several of the study drugs. A pregnancy test is required for female patients of childbearing potential. * Lactating females who plan to breastfeed their infants. * Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation.

## Conditions & Interventions

**Interventions:**

PROCEDURE: Bone Scan, DRUG: Carboplatin, PROCEDURE: Computed Tomography, DRUG: Cyclophosphamide, BIOLOGICAL: Dactinomycin, DRUG: Doxorubicin, DRUG: Etoposide, DRUG: Irinotecan, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Nephrectomy, OTHER: Patient Observation, PROCEDURE: Positron Emission Tomography, PROCEDURE: Ultrasound Imaging, DRUG: Vincristine, PROCEDURE: X-Ray Imaging

**Conditions:**

Stage I Mixed Cell Type Kidney Wilms Tumor, Stage II Mixed Cell Type Kidney Wilms Tumor, Stage III Mixed Cell Type Kidney Wilms Tumor, Stage IV Mixed Cell Type Kidney Wilms Tumor

## More Information

**Contact(s):** ctrrecruit@vcu.edu

**Principal Investigator:**

**Phase:** PHASE3
**IRB**
**Number:**
**System ID:** NCT06401330

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