

# Combination Chemotherapy and Surgery in Treating Young Patients With Wilms Tumor (AREN0534)

# Summary

## Redirection Notice

This page will redirect to <https://www.cancerimagingarchive.net/collection/aren0534/> in about 5 seconds.

This collection contains data from the Children's Oncology Group (COG) Clinical Trial [NCT00945009](https://clinicaltrials.gov/ct2/show/study/NCT00945009), "Combination Chemotherapy and Surgery in Treating Young Patients With Wilms Tumor, " Study Chair: Peter F. Ehrlich, M.D. M.S.C. It was sponsored by NCI and performed by the Children's Oncology Group under study number AREN0534. This phase III trial studies how well combination chemotherapy and surgery work in treating young patients with Wilms tumor. Select patient-level clinical data from this trial is available via the following link: <https://nctn-data-archive.nci.nih.gov/node/728>.

## Trial Description

Children with bilateral Wilms tumor account for 5-7% of all patients with Wilms tumor. Certain patients, with syndromes associated with Wilms tumor development, have been identified to be at increased risk for bilateral tumors. Due to an increased risk for renal failure, patients with bilateral disease at presentation are treated with preoperative chemotherapy in order to preserve renal parenchyma. Although this recommendation was made nearly 30 years ago, patients with bilateral tumors have not been formally studied in prior cooperative trials. Recent evidence suggests that survival of these patients is inferior to similar patients with unilateral tumor. This study is designed to improve the survival of these children, while continuing the emphasis on preserving renal function. Patients were enrolled and imaging studies were centrally reviewed to assess for bilateral renal lesions. They were treated with 3-drug induction chemotherapy (vincristine, dactinomycin, and doxorubicin) for 6 or 12 weeks based on radiographic response followed by surgery and further chemotherapy determined by histology. Radiation therapy was provided for postchemotherapy stage III and IV disease. One hundred eighty-nine of 208 patients were evaluable. Four-year EFS and OS were 82.1% (95% CI: 73.5%–90.8%) and 94.9% (95% CI: 90.1%–99.7%). Twenty-three patients relapsed and 7 had disease progression. After induction chemotherapy 163 of 189 (84.0%) underwent definitive surgical treatment in at least 1 kidney by 12 weeks and 39% retained parts of both kidneys. Surgical approaches included: unilateral total nephrectomy with contralateral partial nephrectomy (48%), bilateral partial nephrectomy (35%), unilateral total nephrectomy (10.5%), unilateral partial nephrectomy (4%), and bilateral total nephrectomies (2.5%). This treatment approach including standardized 3-drug preoperative chemotherapy, surgical resection within 12 weeks of diagnosis and response and histology-based postoperative therapy improved EFS and OS and preservation of renal parenchyma compared with historical outcomes for children with bilateral Wilms tumor.

Before enrollment, real-time central review of diagnostic imaging, pathology (if obtained), and operative notes confirmed the status of BWT. After 6 weeks, cross-sectional imaging was performed and a tumor response was assigned for each kidney. After 4 chemotherapy cycles (12 weeks), repeat cross sectional imaging was performed and definitive surgery was required. Response was based on the Response Evaluation Criteria in Solid Tumor (RECIST 1.1) modified to include 3 lesions per kidney.

## Trial Outcomes

Results of the trial have been reported in the following publication:

- Ehrlich P, Chi YY, Chintagumpala MM, Hoffer FA, Perlman EJ, Kalapurakal JA, Warwick A, Shamberger RC, Khanna G, Hamilton TE, Gow KW, Paulino AC, Gratias EJ, Mullen EA, Geller JI, Grundy PE, Fernandez CV,

Ritchey ML, Dome JS. Results of the First Prospective Multi-institutional Treatment Study in Children With Bilateral Wilms Tumor (AREN0534): A Report From the Children's Oncology Group. *Ann Surg.* 2017 Sep;266(3):470-478. doi: 10.1097/SLA.0000000000002356. Erratum in: *Ann Surg.* 2018 Mar;267(3):e64. PMID: 28795993; PMCID: PMC5629006.

- Ehrlich PF, Chi YY, Chintagumpala MM, Hoffer FA, Perlman EJ, Kalapurakal JA, Tornwall B, Warwick A, Shamberger RC, Khanna G, Hamilton TE, Gow KW, Paulino AC, Gratias EJ, Mullen EA, Geller JI, Grundy PE, Fernandez CV, Dome JS. Results of Treatment for Patients With Multicentric or Bilaterally Predisposed Unilateral Wilms Tumor (AREN0534): A report from the Children's Oncology Group. *Cancer.* 2020 Aug 1;126(15):3516-3525. doi: 10.1002/cncr.32958. Epub 2020 May 27. PMID: 32459384; PMCID: PMC7769115

### Data Access

## Data Access

This is a **limited access** data set. To request access please register an account on the [NCTN Data Archive](#). After logging in, use the "Request Data" link in the left side menu. Follow the on screen instructions, and enter **NCT00945009** when asked which trial you want to request. In step 2 of the Create Request form, be sure to select "Imaging Data Requested". Please contact [NCINCTNDataArchive@mail.nih.gov](mailto:NCINCTNDataArchive@mail.nih.gov) for any questions about access requests.

Data Type	Download all or Query/Filter	License
Images (DICOM, 336 GB)	<a href="#">Download</a> <a href="#">Search</a> (Download requires the <a href="#">NBIA Data Retriever</a> )	<a href="#">NCTN/NCORP Data Archive License (Without Collaborative Agreement)</a>

Click the Versions tab for more info about data releases.

Please contact [help@cancerimagingarchive.net](mailto:help@cancerimagingarchive.net) with any questions regarding usage.

## Additional Resources for this Dataset

The National Cancer Institute (NCI) has created a centralized, controlled-access database, called the [NCTN/NCORP Data Archive](#), for storing and sharing datasets generated from clinical trials of the National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Program (NCORP). Clinical data from the participants in this trial can be found at:

- [NCTN/NCORP Data Archive](#) (Clinical Data)

## Third Party Analyses of this Dataset

TCIA encourages the community to [publish your analyses of our datasets](#). Below is a list of such third party analyses published using this Collection:

- [Annotations for Combination Chemotherapy and Surgery in Treating Young Patients With Wilms Tumor \(AREN0534-Tumor-Annotations\)](#)

### Detailed Description

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Image Statistics	
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Modalities	CT, MR, PT,US
Number of Patients	239
Number of Studies	1176
Number of Series	12093
Number of Images	804789
Images Size (GB)	336

## De-identification of DICOM dates

De-identification of dates for this dataset uses the DICOM Part 3.15 Annex E standard “Retain Longitudinal With Modified Dates Option” which allows dates to be retained as long as they are modified from the original date. TCIA implements this using a technique which de-identifies the dates while preserving the longitudinal relationship between them. Original dates will be first normalized to 01 January, 1960 and then offset relative to the date of registration for each patient. This normalized date system was chosen in order to make it obvious that the dates are not real, and to make it easy to quickly determine how much time has passed between the date of registration and the patients' related imaging studies.

For example, if the real date of a patient's registration was 03/27/2018 and the original imaging Study Date was 03/29/2018 then the "Days from registration" would be +2 and the anonymized TCIA Study Date would become 01/03/1960.

## Insertion of computed "REGISTRATION"/Days offset from registration" value

In addition to modifying the actual date fields in the DICOM header, the "days from registration" values are calculated and stored in the DICOM tag **(0012,0052) Longitudinal Temporal Offset from Event** with the associated tag **(0012,0053) Longitudinal Temporal Event Type** set to "REGISTRATION".

**Note:** If these DICOM tags are not present, DICOM tag **(0012,0050) Clinical Trial Time Point ID** with the associated tag **(0012,0051) Clinical Trial Time Point Description** provides this same information. This inconsistency is due to a change in how dates were handled in the first NCTN trials that were published on TCIA.

### Citations & Data Usage Policy

## Citations & Data Usage Policy

Users must abide by the [TCIA Data Usage Policy and Restrictions](#). Attribution should include references to the following citations:

#### Data Citation

Ehrlich, P., Chi, Y. Y., Chintagumpala, M. M., Hoffer, F. A., Perlman, E. J., Kalapurakal, J. A., Warwick, A., Shamberger, R. C., Khanna, G., Hamilton, T. E., Gow, K. W., Paulino, A. C., Gratias, E. J., Mullen, E. A., Geller, J. I., Grundy, P. E., Fernandez, C. V., Ritchey, M. L., & Dome, J. S. (2021). Combination Chemotherapy and Surgery in Treating Young Patients With Wilms Tumor (AREN0534) [Data set]. The Cancer Imaging Archive. <https://doi.org/10.7937/TCIA.5M9S-6Y97>

#### Publication Citation

Ehrlich, P., Chi, Y. Y., Chintagumpala, M. M., Hoffer, F. A., Perlman, E. J., Kalapurakal, J. A., Warwick, A., Shamberger, R. C., Khanna, G., Hamilton, T. E., Gow, K. W., Paulino, A. C., Gratias, E. J., Mullen, E. A., Geller, J. I., Grundy, P. E., Fernandez, C. V., Ritchey, M. L., & Dome, J. S. (2017). Results of the First Prospective Multi-institutional Treatment Study in Children With Bilateral Wilms Tumor (AREN0534). In *Annals of Surgery* (Vol. 266, Issue 3, pp. 470–478). Ovid Technologies (Wolters Kluwer Health). <https://doi.org/10.1097/sla.0000000000002356>

#### TCIA Citation

Clark, K., Vendt, B., Smith, K., Freymann, J., Kirby, J., Koppel, P., Moore, S., Phillips, S., Maffitt, D., Pringle, M., Tarbox, L., & Prior, F. (2013). The Cancer Imaging Archive (TCIA): Maintaining and Operating a Public Information Repository. In *Journal of Digital Imaging* (Vol. 26, Issue 6, pp. 1045–1057). Springer Science and Business Media LLC. <https://doi.org/10.1007/s10278-013-9622-7>

## Other Publications Using This Data

TCIA maintains [a list of publications](#) which leverage TCIA data. If you have a manuscript you'd like to add please [contact the TCIA Helpdesk](#).

### Versions

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