# Rituximab and Combination Chemotherapy in Treating Patients With Diffuse Large B-Cell Non-Hodgkin's Lymphoma (CALGB50303)

# Summary

**Redirection Notice**

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This collection contains data from the National Cancer Institute Clinical Trial NCT00118209, "Rituximab and Combination Chemotherapy in Treating Patients With Diffuse Large B-Cell Non-Hodgkin's Lymphoma." It was sponsored by NCI's Alliance for Clinical Trials in Oncology under study number CALGB 50303. This randomized phase III trial is studying rituximab when given together with two different combination chemotherapy regimens to compare how well they work in treating patients with diffuse large B-cell lymphoma. Select individual patient-level data from this trial can be requested from the NCTN/NCORP Data Archive.

**Trial Description**

This randomized phase III trial studies rituximab when given together with two different combination chemotherapy regimens to compare how well they work in treating patients with diffuse large B-cell non-Hodgkin's lymphoma. Monoclonal antibodies, such as rituximab, may block cancer growth in different ways by targeting certain cells. Drugs used in chemotherapy work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving rituximab together with combination chemotherapy may kill more cancer cells. It is not yet known which combination chemotherapy regimen is more effective when given with rituximab in treating diffuse large B-cell non-Hodgkin's lymphoma.

Alliance/CALGB 50303 (NCT00118209), an intergroup, phase III study, compared dose-adjusted etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, and rituximab (DA-EPOCH-R) with standard rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) as frontline therapy for diffuse large B-cell lymphoma. Patients received six cycles of DA-EPOCH-R or R-CHOP. The primary objective was progression-free survival (PFS); secondary clinical objectives included response rate, overall survival (OS), and safety. Between 2005 and 2013, 524 patients were registered; 491 eligible patients were included in the final analysis. Most patients (74%) had stage III or IV disease; International Prognostic Index (IPI) risk groups included 26% IPI 0 to 1, 37% IPI 2, 25% IPI 3, and 12% IPI 4 to 5. At a median follow-up of 5 years, PFS was not statistically different between the arms (hazard ratio, 0.93; 95% CI, 0.68 to 1.27; $P = .65$), with a 2-year PFS rate of 78.9% (95% CI, 73.8% to 84.2%) for DA-EPOCH-R and 75.5% (95% CI, 70.2% to 81.1%) for R-CHOP. OS was not different (hazard ratio, 1.09; 95% CI, 0.75 to 1.59; $P = .64$), with a 2-year OS rate of 86.5% (95% CI, 82.3% to 91%) for DA-EPOCH-R and 85.7% (95% CI, 81.4% to 90.2%) for R-CHOP. Grade 3 and 4 adverse events were more common ($P < .001$) in the DA-EPOCH-R arm than the R-CHOP arm, including infection (16.9% *v* 10.7%, respectively), febrile neutropenia (35.0% *v* 17.7%, respectively), mucositis (8.4% *v* 2.1%, respectively), and neuropathy (18.6% *v* 3.3%, respectively). Five treatment-related deaths (2.1%) occurred in each arm.

CT scans of the chest, abdomen and pelvis were utilized for tumor staging for 155 of these patients. Serial fluorodeoxyglucose positron emission tomography (FDG-PET) was conducted at baseline, after 2 cycles of chemotherapy (interim PET [i-PET]), and at end of treatment (EoT) to identify biomarkers of response that are predictive of remission and survival.

**Trial Outcomes**

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


1. Schöder, H., Polley, M.-Y. C., Knopp, M. V., Hall, N., Kostakoglu, L., Zhang, J., Higley, H. R., Kelloff, G., Liu, H., Zelenetz, A. D., Cheson, B. D., Wagner-Johnston, N., Kahl, B. S., Friedberg, J. W., Hsi, E. D., Leonard, J. P., Schwartz, L. H., Wilson, W. H., & Bartlett, N. L. (2020). Prognostic value of interim FDG-PET in diffuse large cell lymphoma: results from the CALGB 50303 Clinical Trial. Blood, 135(25), 2224–2234. https://doi.org/10.1182/blood.2019003277. PMID: 32232481; PMCID: PMC7316220.
2. Bartlett, N. L., Wilson, W. H., Jung, S.-H., Hsi, E. D., Maurer, M. J., Pederson, L. D., Polley, M.-Y. C., Pitcher, B. N., Cheson, B. D., Kahl, B. S., Friedberg, J. W., Staudt, L. M., Wagner-Johnston, N. D., Blum, K. A., Abramson, J. S., Reddy, N. M., Winter, J. N., Chang, J. E., Gopal, A. K., … Leonard, J. P. (2019). Dose-Adjusted EPOCH-R Compared With R-CHOP as Frontline Therapy for Diffuse Large B-Cell Lymphoma: Clinical Outcomes of the Phase III Intergroup Trial Alliance/CALGB 50303. Journal of Clinical Oncology, 37 (21), 1790–1799. DOI: https://doi.org/10.1200/jco.18.01994. Epub 2019 Apr 2. PMID: 30939090; PMCID: PMC6774813.


**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 **NCT00118209** 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 for any questions about access requests.

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Please contact 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 Rituximab and Combination Chemotherapy in Treating Patients With Diffuse Large B-Cell Non-Hodgkin's Lymphoma (CALGB50303-Tumor-Annotations)

**Detailed Description**

## Detailed Description

| Image Statistics | |
|---|---|
| Modalities | CT, PT, OT |
| Number of Patients | 155 |
| Number of Studies | 610 |
| Number of Series | 1944 |
| Number of Images | 509924 |
| Images Size (GB) | 136.2 |

# 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**

Bartlett, N. L., Wilson, W. H., Jung, S.-H., Hsi, E. D., Maurer, M. J., Pederson, L. D., Polley, M.-Y. C., Pitcher, B. N., Cheson, B. D., Kahl, B. S., Friedberg, J. W., Staudt, L. M., Wagner-Johnston, N. D., Blum, K. A., Abramson, J. S., Reddy, N. M., Winter, J. N., Chang, J. E., Gopal, A. K., … Leonard, J. P. (2020). Rituximab and Combination Chemotherapy in Treating Patients With Diffuse Large B-Cell Non-Hodgkin's Lymphoma (CALGB50303) [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/CM65-A013

**Publication Citation**

Bartlett, N. L., Wilson, W. H., Jung, S.-H., Hsi, E. D., Maurer, M. J., Pederson, L. D., Polley, M.-Y. C., Pitcher, B. N., Cheson, B. D., Kahl, B. S., Friedberg, J. W., Staudt, L. M., Wagner-Johnston, N. D., Blum, K. A., Abramson, J. S., Reddy, N. M., Winter, J. N., Chang, J. E., Gopal, A. K., … Leonard, J. P. (2019). Dose-Adjusted EPOCH-R Compared With R-CHOP as Frontline Therapy for Diffuse Large B-Cell Lymphoma: Clinical Outcomes of the Phase III Intergroup Trial Alliance/CALGB 50303. Journal of Clinical Oncology, 37 (21), 1790–1799. https://doi.org/10.1200/jco.18.01994

**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. **The Cancer Imaging Archive (TCIA): Maintaining and Operating a Public Information Repository**, Journal of Digital Imaging, Volume 26, Number 6, December, 2013, pp 1045-1057. DOI: 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.

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