

NCI Clinical Trial

Testing DA-TEDDI-R as a Treatment for Primary Central Nervous System Lymphoma

Do You Have Primary Central Nervous System Lymphoma (PCNSL)?

If so, talk with your doctor about this research study taking place at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland.

What Is Primary Central Nervous System Lymphoma?

PCNSL is a cancer that is caused by types of blood cells, called B lymphocytes, that are not working properly. It is a rare form of diffuse large B-cell lymphoma (DLBCL) that can affect the brain, the eye, the spinal cord, or the fluid surrounding these structures.

Usual Care for Patients with Primary Central Nervous System Lymphoma

Most approaches to treating PCNSL include radiation to the brain and/or chemotherapy with high-dose methotrexate. Both of these treatments have more side effects and are less effective than the treatments for forms of DLBCL that do not affect the central nervous system.

Purpose of the Study

The main purpose of this study is to test safety of ibrutinib (the study drug) given with chemotherapy, without brain radiation. A second purpose is to find out what effects—good and bad—the combination of ibrutinib with chemotherapy has on PCNSL.

The combination of drugs is called **DA-TEDDI-R** (plus cytarabine).

DA stands for dose-adjusted, which describes how the drug doses will be adjusted based on side effects.

T is temozolomide (chemotherapy)

E is etoposide (chemotherapy)

D is Doxil (chemotherapy)

D is dexamethasone (steroid)

I is ibrutinib, that targets tumor B cells

R is rituximab, an antibody that targets or binds to B cells

Cytarabine is a chemotherapy drug given directly into the space around the brain.

Why Was the Study Drug Chosen?

Ibrutinib, an anticancer drug designed to target B-cell cancers, was chosen because it has been effective in treating DLBCL of activated B-cell (ABC) origin. The majority of PCNSL is of ABC origin. (See below for more information.)

What Are the Study Groups?

- Participants in the first group (cohort) will receive DA-TEDDI-R therapy to determine the maximum tolerated dose of the study drug, ibrutinib.
- Participants in the expansion cohort will be assessed for the safety and tolerability of the study drug combination.

Treatment Plan

Drugs: TEDDI-R

Temozolomide, etoposide, Doxil, and rituximab are given intravenously

Dexamethasone and ibrutinib are given orally

All drugs are given every three weeks for up to six cycles

Drug: Cytarabine

Cytarabine is given into the space around the brain via Ommaya reservoir (intrathecal therapy) on days 1 and 5 of cycles 2 through 6

Benefits of Taking Part in This Study

Potential benefits might include shrinking of your tumor and/or a reduction in symptoms caused by the cancer.

Costs of Taking Part in This Study

You will be responsible for covering the costs of your initial visit to the NIH Clinical Center. If you enroll in this study, your travel to the NIH and study treatment will be provided at no charge to you. *Please note that you will not be paid to take part in this study.*

Risks of Taking Part in This Study

If you choose to take part in this study, there are several potential risks:

- You may lose time at work or home and/or spend more time in the hospital or doctor's office.

- The drugs used may affect different parts of your body, such as your liver, kidneys, heart, and blood.
- You could have side effects from the drugs.

You Can Stop at Any Time

If for any reason you change your mind about being part of the study, you can stop at any time. In turn, we may ask you to stop the study if we believe it is in your best interest, if you do not follow the study rules, or if the study is stopped altogether.

For More Information and Full Eligibility Criteria:

- See the [full study record](#) on ClinicalTrials.gov
- Contact Margaret Shovlin, RN, at mshovlin@mail.nih.gov or 301-594-6597
- Contact the [National Cancer Institute Cancer Information Service](#) at 1-800-4-CANCER (1-800-422-6237)

Abbreviations used in this information sheet

DLBCL—Diffuse large B-cell lymphoma is a common type of aggressive B-cell lymphoma arising from defective B-cells called lymphocytes.

PCNSL—Primary central nervous system lymphoma is a less common subtype of DLBCL that presents in the central nervous system (CNS).

ABC—Activated B cell is a cell of origin for DLBCL and PCNSL. A cell of origin is the type of cell from which the lymphoma originates.



National Cancer Institute