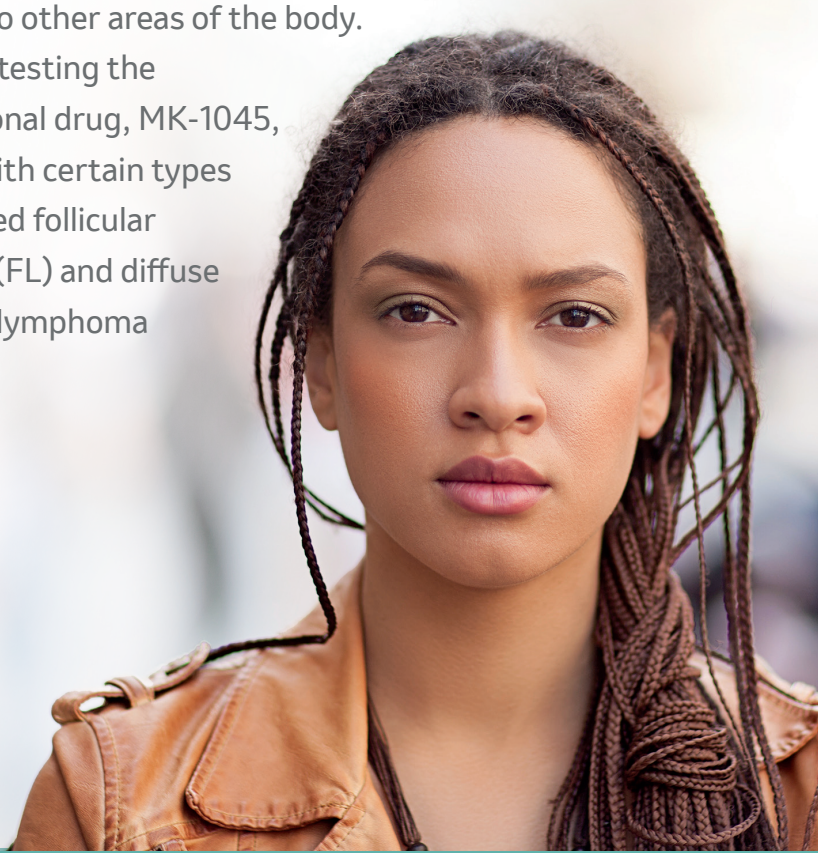
MK1045-008

Learn about a clinical trial for **Non-Hodgkin Lymphoma**

In this brochure, you will learn about **Non-Hodgkin Lymphoma (NHL)** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational drug is safe and may help slow down or stop your NHL from spreading to other areas of the body.

This trial is testing the investigational drug, MK-1045, in people with certain types of NHL called follicular lymphoma (FL) and diffuse large B cell lymphoma (DLBCL).



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What is NHL?

NHL is a slow-growing cancer that starts in cells in your immune system. These cells are called B-cells, which are white blood cells that help your body fight infections.

NHL happens when:

- B-cells in the lymph nodes have a harmful change in their DNA.
- This causes them to grow and make copies faster than normal.
- This leads to too many harmful cells in the immune system and a low number of healthy cells, so the body's immune system does not work as normal.

NHL usually causes enlarged lymph nodes and can spread to bone marrow, blood, or other organs.

What is relapsed or refractory (r/r) cancer?

Relapsed means the cancer has come back after previous treatment. Refractory means the cancer has not gotten better with previous treatment. Relapsed or refractory is often shortened to r/r.

What are my treatment options?

If you have relapsed or refractory NHL, your care team will talk about your treatment options with you and those close to you.

Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if the cancer has spread and how far
- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms
- Features of your cancer cells (called biomarkers) that may help guide your treatment

Your care team may offer you 1 or more of these treatments:

- **Local therapies** – treatment directed at the site of the cancer to destroy it
- **Targeted therapy** – treatment that works on specific cells to stop them from growing
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing
- **Radiation therapy** – treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. This would only be used to treat symptoms related to tumor growth.
- **Palliative care** – this is care that does not directly treat NHL, but aims to ease pain and symptoms with a focus on the person's quality of life.
- **Watchful waiting** - your care team might wait and watch the cancer before they use any treatment (also called active surveillance)
- **Clinical trials**, such as this one

Talk to your doctor to find out which treatment is right for you.

What is a clinical trial?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

All about this clinical trial

What is the goal of this clinical trial?

The goal of this trial is to learn if an investigational drug, MK-1045, is safe and may help slow down or stop the NHL from spreading to other areas of the body. This trial is testing different doses of MK-1045 to find a recommended dose for additional testing in this and other clinical trials.

MK-1045 is experimental. It has not been approved to treat any kind of cancer.

Researchers will compare:

- Different dose strengths of MK-1045
- Different schedules for giving MK-1045 (different number of weeks between doses)
- Different ways to give MK-1045: either as an IV (by a needle into a vein) or shot under the skin (subcutaneous injection)

What is the study treatment being researched?

The investigational drug is MK-1045. Everyone in this trial will get MK-1045.

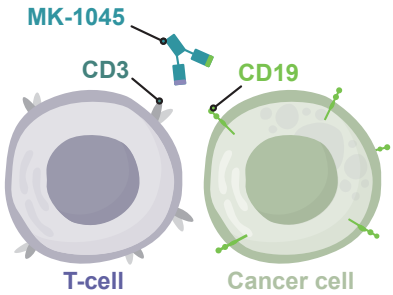
About MK-1045

The investigational drug, MK-1045, is a type of investigational drug called an immunotherapy, which is a medicine that helps your immune system fight cancer.

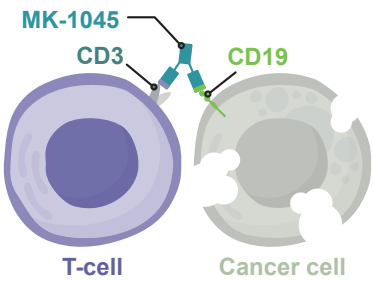
How researchers think MK-1045 may work

1. T-cells are cells in your immune system that help your body fight off disease, such as cancer. They recognize and destroy disease cells. T-cells have a protein on their surface called CD3.
2. Certain types of cancer cells often have a protein on their surface called CD19.
3. Researchers are studying if the investigational drug, MK-1045, may bind to both CD3 on T-cells and CD19 on cancer cells, forming a link that helps the T-cells recognize the cancer cells.
4. By forming this link, MK-1045 may help T-cells attack and destroy cancer cells.

Another way to think about MK-1045



MK-1045 may form a link between the **T-cell** and the **cancer cell** by binding to the cell surface proteins.



By binding to the surface proteins, a link may be formed by **MK-1045** **MK-1045** that may help **T-cells** attack and destroy **cancer cells**.

Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation.

For example, you must:

- Be at least 18 years old
- Have FL or DLBCL that has not responded to, or has returned after, previous treatment

Your trial staff will do tests to see if you are able to join this trial.

You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- How well you tolerate the investigational drug

You will get the investigational drug for about 1 year. After the end of treatment phase, your doctor will continue to follow up with you to check on your health.

What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the investigational drug might be working for you.

During your trial visits, you may get:

- Your assigned investigational drug
- Blood and/or urine tests
- Physical exams
- Electrocardiograms (ECGs) (a quick, painless test that measures your heart's electrical activity)
- Imaging tests, such as CT scans, MRIs, and FDG-PET scans
- Bone marrow or lymph node biopsies (doctors take a sample of tissue from your body to test it)
- Bone marrow aspirates (doctors take a sample from the liquid part of your bone marrow to test it)
- Overnight hospitalization, so that your doctor can check on your health after receiving the investigational treatment

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the investigational drug may work over time.

What study treatment will I get?

You will visit the trial site on a regular schedule so that the trial doctors can see how the investigational drug might be working for you. Everyone in this trial will get the investigational drug, MK-1045. Which group you are placed in depends on what kind of cancer you have and when you join the trial.

This trial has four groups:

Groups 1, 2, and 3 are for people with FL.

- **Group 1** will get MK-1045 by IV.
  - **Group 1** will test 3 different doses of MK-1045. The trial doctor or staff will discuss this with you. A computer will decide which dose you get. You have an equal chance of getting each dose.
  - If you are in **Group 1**, you will get MK-1045 every week. If your cancer responds to treatment, then it may be given every 2 weeks.
- **Group 2** will get MK-1045 by IV.
  - If you are in **Group 2**, you will get MK-1045 every week for the first three doses.
  - After that, you will get it every 2 weeks. If your cancer responds to treatment, then it may be given every 4 weeks.
- **Group 3** will get MK-1045 by injection and by IV.
  - If you are in **Group 3**, you will start by getting the MK-1045 injection every week for about 8 weeks (2 months).
  - After that, the way you get MK-1045 will change, and you will get it by IV every week. If your cancer responds to treatment, then it may be given every 2 weeks.

Group 4 is for people with DLBCL and will get MK-1045 by IV.

- **Group 4** will test 3 different doses of MK-1045. The trial doctor or staff will discuss this with you. A computer will decide which dose you get. You have an equal chance of getting each dose.
  - If you are in **Group 4**, you will get MK-1045 every week. If your cancer responds to treatment, then it may be given every 2 weeks.

There are two possible serious side effects of MK-1045:

- Cytokine release syndrome (CRS), which is a reaction to a drug where your immune system releases substances into your blood called cytokines. This can cause your body to feel sick. Symptoms include:
  - Fever
  - Lightheadedness
  - Nausea (which means feeling sick to the stomach)
  - Headaches
  - Rashes on skin
  - Fast heartbeat
  - Low blood pressure
  - Trouble breathing
- ICANS (ICANS refers to brain-related side effects due to a strong reaction of the immune system caused by the drug, which are usually temporary). Common symptoms of ICANS are:
  - Confusion or trouble thinking clearly
  - Difficulty speaking or understanding words
  - Trouble writing or following instructions
  - Feeling very sleepy or hard to wake up
  - Shaking or tremors
  - Seizures (in severe cases)
  - Swelling in the brain (rare but serious)

Please refer to the Informed Consent for additional possible side effects and all other materials provided that address these and other side effects.

What is a tissue sample and why is it part of this trial?

If you are eligible and join the trial, the study doctor will ask you for tissue samples. Tissue, such as skin, hair, nails, blood, urine or tumors, are found in your body and are collected as they may help researchers understand diseases and find ways to help prevent and treat them in people.

For this study, your study doctor will collect tumor and blood tissue samples. These may be new tissue samples, or they may ask to use tissue that was collected before. Tissue you provide for the study will be stored for research only and will continue to be tracked according to your study code number.

Thank you for learning about relapsed or refractory NHL and this clinical trial

You can use this brochure to talk with your doctor about this trial.



Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

Notes

Notes

To learn more

To learn more about this trial, you can

- Talk to your doctor
- Visit **www.merckclinicaltrials.com**
- Scan this QR code:

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