

**MT2023-46: A Phase 3, multicenter, randomized, open-label, parallel group, treatment study to assess the efficacy and safety of the lifileucel (LN-144, autologous tumor-infiltrating lymphocytes [TIL]) regimen in combination with pembrolizumab compared with pembrolizumab monotherapy in participants with untreated, unresectable or metastatic melanoma**

**Status:** Recruiting

## Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 18 years and over

This study is NOT accepting healthy volunteers

### Inclusion Criteria:

- 18 to 70 years old (in certain cases, people older than 70 may be able to enroll) - diagnosis of Stage IIIC, IIID, or IV unresectable or metastatic melanoma - may not be able to do physically strenuous activity but walking and able to do light or sedentary work, e.g., light house work, office work - participants of childbearing potential or those with partners of childbearing potential must be willing to practice an approved method of highly effective birth control - see link to [clinicaltrials.gov](https://clinicaltrials.gov) for complete Inclusion criteria

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### Exclusion Criteria:

- melanoma of uveal/ocular (eye) origin - symptomatic untreated brain metastases - had another cancer in the previous 3 years - history of allogeneic cell or organ transplant - see link to [clinicaltrials.gov](https://clinicaltrials.gov) for complete exclusion criteria

## Conditions & Interventions

### Conditions:

Cancer

### Keywords:

Melanoma, Metastatic Melanoma, Clinics and Surgery Center (CSC)

## More Information

**Description:** We want to find out whether lifileucel is safe and works in treating untreated, unresectable or metastatic melanoma. Lifileucel is a type of medicine, known as immunotherapy, that uses your body's immune system to fight cancer. Lifileucel is also called "tumor infiltrating lymphocytes" (TIL) and is made up of specialized white blood cells known as lymphocytes or "T cells" obtained from a piece of your tumor. T cells are a part of your immune system that help your body fight against infections and diseases including fight cancer.

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**Phase:** PHASE3

**IRB Number:** STUDY00021773

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