

# Clinical Trials

Clinical trials formally test whether a drug is safe and effective. Some patients enroll to gain access to cancer treatments that are not otherwise available. Each trial has specific eligibility requirements. Two categories of clinical trials are:

**Adjuvant Trials** For patients who do not have evidence of cancer but are at risk for recurrence. Two randomized MCC adjuvant trials are:

- **ADAM**- Avelumab (or placebo) after initial treatment of high-risk MCC
- **STAMP**- Pembrolizumab (or observation) after surgery

**T-cell Therapy** In cases that are non-responsive to approved immune therapies, a patient's own T cells are re-programmed to recognize and kill MCC cells.

- **ATTAC trial**- For virus-positive MCC, patients receive transgenic T-cells to further boost the immune system.

**More clinical trials and details at:**

- [www.merkelcell.org/treatment/clinical-trials](http://www.merkelcell.org/treatment/clinical-trials)
- [www.cancer.gov](http://www.cancer.gov)
- [www.emergingmed.com](http://www.emergingmed.com)

## Resources

### **Merkelcell.org**

Up-to-date MCC information curated by Seattle-based clinicians and researchers who have cared for over 1000 MCC patients.

[www.merkelcell.org](http://www.merkelcell.org)

### **National Cancer Institute**

Comprehensive cancer information from the U.S. government's principal cancer research agency.

800-422-6237

[www.cancer.gov](http://www.cancer.gov)

### **CancerCare**

Non-profit providing telephone, online and face-to-face counseling, support groups, education, and financial/co-pay assistance.

800-813-HOPE (800-813-4673)

[www.cancercare.org](http://www.cancercare.org)

### **American Cancer Society**

Nationwide organization providing cancer research publications, patient services, and education on early detection and treatment.

800-227-2345

[www.cancer.org](http://www.cancer.org)

### **Cancer.net**

Patient information from the American Society of Clinical Oncology.

888-651-3038

[www.cancer.net](http://www.cancer.net)

### **The Skin Cancer Foundation**

Get an overview about MCC, plus information about diagnosis, treatment, and risks.

[www.skincancer.org](http://www.skincancer.org)

### **Medicine Assistance Tool**

Dedicated search engine with financial assistance resources for medications.

[www.medicineassistancetool.org](http://www.medicineassistancetool.org)

# About Merkel Cell Carcinoma

## Informational Pamphlet

### Seattle MCC Team



*Example of Merkel cell carcinoma on the hand*

**September 2021**



Left to right: Merkel cell carcinoma of the cheek and eyelid

## Disease Background

Merkel cell carcinoma (MCC) is a rare, aggressive type of skin cancer. MCC arises from uncontrolled growth of cells that share characteristics with normal Merkel cells of the skin.

The disease usually appears as a painless bump, often on sun-exposed areas such as the face, neck, or arms. The tumor may be skin-colored, purple, or red.

### Risk Factors

Associated factors include: age >65, fair skin, extensive sun exposure, chronic immune suppression, and the Merkel cell polyomavirus is present in 80% of cases.

## Diagnosis

**Skin biopsy.** A small sample of affected skin is removed and examined by a pathologist to determine if it contains cancerous cells.

Other tests may be conducted to determine whether MCC has spread beyond the skin:

**Imaging.** A PET/CT scan is recommended at time of diagnosis for most patients.

**Sentinel lymph node biopsy.** A radioactive dye is injected near the tumor. The first lymph nodes to receive the dye (sentinel nodes) are removed and examined under a microscope for presence of cancer.

## Treatment

Treatment options often depend on whether the MCC has spread beyond the skin.

Approaches vary between patients and commonly include a combination of:

- **Surgery**
- **Radiation** – reduces risk of recurrence at primary site and/or nearby lymph nodes
- **Immunotherapy** – medications boost the immune system to fight MCC
- **Chemotherapy** – can control advanced MCC if immunotherapy is not an option

## Surveillance

Several methods can detect recurrences.

- **Merkel polyomavirus antibody (serology) test** – blood test that tracks Merkel virus antibodies to detect recurrences early. Also known as the ‘AMERK’ test.
- **Imaging** – PET and/or CT scans
- **Physical exam** – clinician conducted exams of skin, abnormal lesions and nodes

## Exciting MCC Developments

### Circulating Tumor DNA (ctDNA)

This test detects DNA released by Merkel cell carcinoma (MCC) tumor cells into the blood. The presence and quantity of MCC tumor-specific DNA mutations in a patient’s blood suggest residual or recurrent MCC. This blood test works for both virus-positive and virus-negative patients to monitor response to treatment or to detect early recurrence.

### Personalized Risk Calculator

An online tool to assess an individual patient’s risk of MCC recurrence at any given time after diagnosis. Available at [merkelcell.org/recur](http://merkelcell.org/recur).

### “Therapeutic” Vaccine

After initial surgery/radiation, we currently have no treatments to minimize the chance of MCC recurrence. A therapeutic vaccine targeting the Merkel virus could help the immune system recognize and destroy any remaining cancer cells in the body and is on target for a 2022 clinical trial.

### DNA Damage Response Inhibitor

New drugs which inhibit a cancer’s ability to respond normally to DNA damage may also stimulate an anti-tumor immune response. One such drug, an ATR inhibitor, is entering phase I trials, and we hope MCC patients may receive it in the upcoming year. We are working with the Cancer Immunotherapy Trials Network (CITN) to develop a subsequent phase II trial to test this ATR inhibitor as a treatment for patients with MCC that does not respond to immunotherapy.