

The Radiation Therapy Oncology Group, known as RTOG, is a national cancer research organization funded by the National Cancer Institute. RTOG member investigators come from over 300 of the leading academic and community medical facilities in the United States, Canada, and internationally.

RTOG has played a key role in the development of new cancer treatments for over 40 years. The goal of the group is to increase survival and improve the quality of life for patients diagnosed with cancer.

Over 60 RTOG staff members provide administrative, data management, statistical, quality assurance, and protocol development support for group investigators. The administrative and biostatistical staff is headquartered in the American College of Radiology Clinical Research Center in Philadelphia, PA. RTOG receives National Cancer Institute funding as well as corporate support.

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RTOG 0539

A Phase II Trial of Observation for Low-Risk Meningiomas and of Radiotherapy for Intermediate- and High-Risk Meningiomas

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SURGERY FOR LOW-RISK & RADIATION FOR HIGHER-RISK *patients with* MENINGIOMAS

RTOG 0539

Does surgery result in a good outcome for patients with low-risk meningiomas, and does radiation improve outcome for patients with higher-risk meningiomas?

*Information for
Patients*

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Meningiomas are tumors that usually arise from the lining of the brain or spinal cord, an area known as the meninges. The standard treatment for patients with meningiomas varies.

Treatment for all patients involves surgery to remove as much of the tumor as possible. For patients whose tumors cannot be completely removed, were removed but then grew back, or were completely removed but were a higher grade, further treatment can involve radiation therapy. However, there is controversy in the medical community over which patients should receive radiation and which patients should receive only surgery.

The goal of this research study is to find out:

- Whether the standard practice of surgery alone results in a good outcome for patients with low-grade tumors that were completely or partially removed for the first time; and
- Whether surgery followed by radiation therapy results in a good outcome for patients with
 - Higher-grade tumors that were completely or partially removed for the first time, or
 - Low-grade tumors that have grown back after surgery.

Many institutions worldwide are participating in this trial sponsored by the RTOG. Approximately 165 patients are expected to take part in this study.

Joining this study is entirely voluntary. If you are interested in participating, or have additional questions, please talk to your doctor.

Frequently Asked Questions

What is a clinical trial?

Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?

In addition to having a meningioma, there are other eligibility requirements to participate in this study. Your doctor can determine whether you meet these requirements.

What are the possible treatments?

Based on the grade of your tumor, how much of your tumor was removed at surgery, and whether or not your tumor has grown back, you will be placed in one of three groups. Treatment will depend on what group you are in.

Group I (Low Risk)

- Patients with a grade I meningioma that has been completely or partially removed for the first time.

If you are in Group I, you will be observed.

Group II (Intermediate Risk)

- Patients with a grade II meningioma that has been completely removed for the first time, or
- Patients with a grade I meningioma that has grown back after surgery.

If you are in Group II, you will receive radiation therapy. Radiation therapy will occur Monday through Friday for 30 treatments. The total radiation dose will be 54 Gy.

Group III (High Risk)

- Patients with a grade III meningioma, regardless of whether it has grown back after

surgery and how much tumor was removed;

- Patients with a grade II meningioma that has grown back after surgery, regardless of how much tumor was removed; or
- Patients with a grade II meningioma that has been partially removed for the first time.

If you are in Group III, you will receive radiation therapy. Radiation therapy will occur Monday through Friday for 30 treatments.

The total radiation dose will be 60 Gy.

Are there side effects?

Possible risks for patients who receive radiation therapy for brain tumors include scalp redness or soreness; hair loss; ear/ear canal reactions; fatigue; tiredness or sluggishness; and temporary aggravation of brain tumor symptoms such as headaches, seizures, or weakness. Your doctor will review all of the side effects.

How often will I be seen?

If you are in Groups II or III, you will receive radiation therapy for about 6 weeks. Patients in all groups will be followed closely for 3 years and will be seen at least yearly for 10 years from then on.

How much will it cost?

The treatment costs for this study are generally considered part of normal brain tumor care and will be billed to your insurance carrier. As with all brain tumor therapies, expenses not covered by your insurance or Medicare may be billed to you.