Navigating Clinical Trials

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Participation in a clinical trial could be an important option for someone with ocular melanoma.
But, finding and joining the right clinical trial can be challenging.
Challenges in finding a clinical trial

- Is your treating physician “tuned in” to clinical trials?
- Where are the best places to look for information?
- The information can be overwhelming.
- Figuring out if you are eligible can be difficult.
- Making contact with a study team can take time.
What Are Clinical Trials?

- A series of steps that potential new treatments go through after laboratory and animal testing.
- Clinical trials are research that involves people.
- Clinical trials use a study plan that follows strict guidelines.
- A clinical trial must first be approved by an Institutional Review Board before enrolling any patients at a site.
Are Clinical Trials Safe?

- Federal guidelines
- Informed Consent
- Approval by IRB
- Monitoring by PI, IRB, Data Safety Monitoring Board, FDA
Every Trial Has a Study Protocol

- The purpose
- Who is eligible
- How many people can participate
- What the study drug/device/therapy is and exactly how it is used
- What other drugs/devices are involved and how they will be used
- What tests and procedures are involved
- What information is gathered and when
## APPENDIX B: STUDY FLOW CHART

<table>
<thead>
<tr>
<th>Visit</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timepoint (Day)</td>
<td>-14 to -1; -7 to -1 (for patients aged &lt; 2 years)</td>
<td>1</td>
<td>2</td>
<td>7 to 10</td>
<td>15 to 18</td>
</tr>
<tr>
<td>Assessments</td>
<td>Screening/Baseline</td>
<td>Randomization/Treatment/Surgical Procedure</td>
<td>Control Visit</td>
<td>Final Visit</td>
<td>Follow-up Telephone Contact</td>
</tr>
<tr>
<td>Informed Consent / Assent</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion/Exclusion Criteria</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Demography</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA status</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical history</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior and concomitant medication recording</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Hematology, Serum chemistry</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Urinalysis</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Pregnancy test (urine)</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Physical examination</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Vital signs</td>
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<td></td>
<td></td>
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<tr>
<td>Height and weight</td>
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<td></td>
<td></td>
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<tr>
<td>12-lead ECG</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Randomization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Study drug administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Surgical operation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Record time of recovery (T0)</td>
<td></td>
<td></td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>PK for neonates</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
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<tr>
<td>Record efficacy parameters</td>
<td></td>
<td></td>
<td>Recording up to 24h</td>
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<td></td>
</tr>
<tr>
<td>Patient Diary</td>
<td>Instruction</td>
<td>Filled in up to 24h</td>
<td></td>
<td>Collection</td>
<td></td>
</tr>
<tr>
<td>Adverse event recording</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Types of Clinical Trials

- To prevent
- To find and diagnose
- To treat
- To manage

- New drugs
- New surgeries or devices
- New therapies
- New combinations
# Phases of Clinical Trials

<table>
<thead>
<tr>
<th>Phase</th>
<th>Typical Purposes</th>
<th>Size</th>
</tr>
</thead>
</table>
| I     | Determine safe dose(s)  
Initial evaluation of safety  
Identify side effects | <80        |
| II    | Initial determination of efficacy in diseased population  
Further evaluation of safety | 100-300    |
| III   | Confirmation of efficacy  
Comparison with common approved treatments  
Further safety evaluations  
Randomized | 1000-3000 |
| IV    | Post-market study to further determine optimal use |            |
How do I find a clinical trial?
Working with your primary or diagnosing physician

- Consider trial options initially offered by your physician
- Ask specifically if they aren’t offered
- Don’t be afraid to seek a second opinion
- Gather as much information as possible about OM on your own
Finding out about trial options on you own

- Key Websites:
  - www.clinicaltrials.gov
  - www.cancer.gov
  - bethesdatrials.cancer.gov

- General information about clinical trials
- Find-a-Trial functions
http://www.cancer.gov/clinicaltrials
http://www.cancer.gov/clinicaltrials
http://www.cancer.gov/clinicaltrials

Randomized Study Comparing Two Dosing Schedules for Hypofractionated Image-Guided Radiation Therapy

Basic Trial Information

Summary

The purpose of this study is to find out which way of giving high-dose radiation works best for treatment of cancer that has spread to the bone, spine, soft tissue, or lymph nodes. This study will look at the effects, good and/or bad, of giving 27 Gy in three fractions (3 days) or 24 Gy in one fraction (1 day) using image-guided intensity-modulated radiotherapy (IG-IMRT). IG-IMRT is radiation that is given directly to the cancer site and reduces the exposure to normal tissue. Currently there are no studies that compare the effects of giving radiation in either hypofractionated doses (higher total doses of radiation spread out over several treatment days) or a single-fraction dose (entire radiation dose given in one treatment session).

Eligibility Criteria

Inclusion Criteria

- Histologically or cytologically confirmed diagnosis of cancer (including epithelial carcinoma, sarcoma, and melanoma). The diagnosis can be done at MSKCC or at participating institutions.
- Sites of metastatic disease to be treated on protocol are limited to bone, spine, soft tissue, and lymph nodes only.
- Patients with American Joint Committee on Cancer (6th edition, 2002) Stage IV cancer with distant metastases
- Age 18 years or older
- Life expectancy ≥ 3 months
**Trial Contact Information**

**Trial Lead Organizations/Sponsors**

**Memorial Sloan-Kettering Cancer Center**

Ospedale di Ciranello

Michael J. Zelefsky, Principal Investigator

Michael Z. Zelefsky, MD
Ph: 212-639-6802

Yoshiya Yamada, MD
Ph: 212-639-2960

**Trial Sites**

**U.S.A.**

**New York**

**Memorial Sloan-Kettering Cancer Center**

Michael J. Zelefsky, M.D.
Ph: 212-639-6802

Yoshiya Yamada, MD
Ph: 212-639-2960

Italy

**University of Pisa**

Carlo Greco, MD
Ph: 212-639-6802

Carlo Greco, MD
Principal Investigator

**Link to the current ClinicalTrials.gov record.**

NLM identifier: NCT01222248

Information obtained from ClinicalTrials.gov on December 14, 2011

**Note:** Information about this trial is from the ClinicalTrials.gov database. The versions designated for health professionals and patients contain the same text. Minor changes may be made to the ClinicalTrials.gov record to standardize the names of study sponsors, sites, and contacts. Cancer.gov only lists sites that are recruiting patients for active trials, whereas ClinicalTrials.gov lists all sites for all trials. Questions and comments regarding the presented information should be directed to ClinicalTrials.gov.
Search for CCR Trials at NIH

CCR Clinical Trial Summaries

The NCI Center for Cancer Research (CCR) conducts more than 150 cancer clinical trials at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland. Cancer clinical trials that take place at the NIH Clinical Center are open to patients with cancer, regardless of where they live in the United States.

Cancer clinical trials are available for many types of cancer including the ones found below. You may search for clinical trial summaries, which include trial-specific details such as the protocol title, key eligibility criteria, study outline, and study contact names and numbers. If you need further assistance, call our toll-free number 1-888-NCI-01937 (1-888-624-01937) to be connected to a referral coordinator appropriate for your diagnosis.

You may view all trials, use the advanced search tool, or enter your search criteria below:

- **Type of Cancer/Disease:**
- **Search:** (optional)

Only one word, a specific drug name, protocol number, or doctor's name

For additional studies that may be appropriate for your disease type, please search under **Solid Tumor**.

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ClinicalTrials.gov is a registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals.

**Search for Clinical Trials**

Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has 121,633 trials with locations in 179 countries.

**Investigator Instructions**

Get instructions for clinical trial investigators/sponsors about how to register trials in ClinicalTrials.gov. Learn about mandatory registration and results reporting requirements and US Public Law 110-85 (FDAAA).

**Background Information**

Learn about clinical trials and how to use ClinicalTrials.gov, or access other consumer health information from the US National Institutes of Health.
Intravenous or Hepatic Arterial Infusion of Fotemustine in Treating Patients With Unresectable Liver Metastases From Eye Melanoma

The recruitment status of this study is unknown because the information has not been verified recently.

Verified June 2009 by National Cancer Institute (NCI). Recruitment status was Recruiting.


<table>
<thead>
<tr>
<th>Sponsor</th>
<th>European Organization for Research and Treatment of Cancer - EORTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information provided by</td>
<td>National Cancer Institute (NCI)</td>
</tr>
<tr>
<td>ClinicalTrials.gov Identifier</td>
<td>NCT00110123</td>
</tr>
</tbody>
</table>

### Purpose

**RATIONALE.** Drugs used in chemotherapy, such as fotemustine, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving the drugs in different ways may kill more tumor cells. It is not yet known whether giving fotemustine as an intravenous infusion is more effective than giving it as a hepatic arterial infusion in treating liver metastases.

**PURPOSE.** This randomized phase III trial is studying intravenous infusion of fotemustine to see how well it works compared to hepatic arterial infusion of fotemustine in treating patients with unresectable liver metastases from eye melanoma.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraocular Melanoma</td>
<td>Drug: fotemustine</td>
<td>Phase III</td>
</tr>
<tr>
<td>Metastatic, Cancer</td>
<td>Drug: isolated perfusion</td>
<td></td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized

Masking: Open-Label

Primary Purpose: Treatment

Official Title: Intravenous Versus Intra-Arterial Fotemustine Chemotherapy in Patients With Liver Metastases From Uveal Melanoma. A Randomized Phase III Study of the EORTC Melanoma Group.
IRB Issues to Consider

- Neurologic function score 0, 1, or 2.
- Patients receiving glucocorticoids should be tapered to the lowest possible dose, or altogether, as judged by the participating physician. If glucocorticoid dose is adjusted or given for the first time, patient must remain on stable dose of glucocorticoids for at least 3 days prior to initial Neurocognitive Assessment Protocol (NAP), CT and MR imaging.

Exclusion Criteria:
- Major medical illnesses or psychiatric impairments, which in the investigators opinion will prevent administration or completion of the protocol therapy and/or interfere with follow-up.
- For patients who have undergone subtotal resection, residual disease must be 4 cm in maximum diameter.
- Inability to obtain histologic proof of primary malignancy.
- Patients with leptomeningeal metastases documented by MRI or cerebral spinal fluid (CSF) evaluation.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00651113

Locations
United States, Virginia
Massey Cancer Center/Virginia Commonwealth University
Richmond, Virginia, United States, 23298

Sponsors and Collaborators
Virginia Commonwealth University

Investigators
Principal Investigator: Mitchell S. Anschel, MD  Massey Cancer Center

More Information

Additional Information:
Massey Cancer Center Clinical Trials

No publications provided

Responsible Party: Mitchell S. Anschel, MD, Massey Cancer Center/Virginia Commonwealth University
ClinicalTrials.gov Identifier: NCT00651113  History of Changes
Other Study ID Numbers: MCC-10855
Study First Received: December 20, 2007
Results First Received: October 9, 2010
Last Updated: January 27, 2011
Health Authority: United States: Institutional Review Board

Keywords provided by Virginia Commonwealth University:
- whole brain radiotherapy
- neural stem cell
- brain metastases
Joining a Trial
Joining a Trial

- Initial contact with study team
- Pre-screening by phone
- Talk about the study and informed consent
- Study activities begin
Informed Consent for Clinical Research
Georgetown University

INSTITUTION: (Name of all hospitals participating)

INTRODUCTION
You are invited to consider participating in this study. The study is called (“Title of Study”). Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary;

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;

(c) You may decline to participate or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing your access to care, treatment and health services unrelated to the research.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form.
Informed Consent Forms

- Title, sponsor, principal investigator
- Purpose
- How many people will participate?
- What exactly is involved in the study?
- How long will I be in the study?
- What are the risks of being in the study?
- Are there any benefits to taking part in the study?
- What other options are there?
- Confidentiality
- What are the costs?
- Research related injury
- Are there any payments for participation?
- What are my rights as a participant?
- Who do I call with questions or problems?
Informed Consent Process

• Take your time!
• Listen and read carefully, ask questions
• Make sure you understand if it’s randomized
• Consider risks and possible benefits
• Consider impact of participation
• Make sure you are clear about treatment options
• Make sure you understand potential costs
• Discuss with your treating physician, develop a strategy
Once you are in a study

- Maintain open communication with the study team
- Be compliant with the protocol
- You are in charge regarding your participation
- Review your medical bills carefully
- Ask questions to confirm that your referring physician is being kept informed
http://clinicaltrials.georgetown.edu