

# Open Clinical Trials for Mesothelioma

## Video-Assisted Surgery or Talc Pleurodesis in Treating Patients with Malignant Mesothelioma

STUDY ID: NCT00821860

STUDY PURPOSE: Video-assisted surgery to remove part of the tissue layer covering the inside of the chest cavity may be effective in treating pleural effusion and cause less damage to normal tissue. Talc pleurodesis may keep fluid from building up in the chest cavity. It is not yet known which therapy is more effective in treating pleural effusion caused by malignant mesothelioma. This randomized phase III trial is studying video-assisted surgery to see how well it works compared with talc pleurodesis in treating patients with malignant mesothelioma.

STUDY TYPE: Interventional

STUDY CONTACT: Robert Winter, MD. Papworth Hospital; Cambridge, England, UK CB3 8RE. Tel. 44-1480-364-821.

## Everolimus in Treating Patients with Pleural Malignant Mesothelioma That Cannot Be Removed By Surgery

STUDY ID: NCT00685204

STUDY PURPOSE: This phase II trial is studying how well everolimus works in treating patients with pleural malignant mesothelioma that cannot be removed by surgery.

STUDY TYPE: Interventional

STUDY CONTACT: Sai-Hong I. Ou, MD, PhD. Chao Family Comprehensive Cancer Center; Orange, CA 92868. Tel. 877-827-8839.

## An Efficacy Study of Milataxel (TL139) Administered Orally for Malignant Mesothelioma

STUDY ID: NCT00685204

STUDY PURPOSE: Milataxel is a new taxane that may have several advantages over the currently available taxanes. The current study is designed to determine the response rate of oral Milataxel in patients with malignant mesothelioma. The study specifically targets patients who have recurring or progressive disease following previous chemotherapy.

STUDY TYPE: Interventional

STUDY CONTACT: Harvey Pass, MD. New York University Cancer Center; New York, NY 10016. Tel. 212-731-5414.



## A Phase II Study of the Association of Glivec® Plus Gemzar® in Patients with Unresectable, Refractory, Malignant Mesothelioma

STUDY ID: NCT00551252

**STUDY PURPOSE:** The purpose of this study is to evaluate the antitumor activity of a combination of Imatinib mesylate and Gemcitabine in patients with unresectable malignant mesothelioma expressing either PDGFR-beta or C-kit.

**STUDY TYPE:** Interventional

**STUDY CONTACT:** Camillo Porta, MD. Medical Oncology, IRCCS, San Matteo University Hospital Foundation; Pavia, Italy 27100. Tel. +39-0382-501-355.

## Immunotoxin Therapy, Pemetrexed, and Cisplatin in Treating Patients with Malignant Pleural Mesothelioma That Cannot Be Removed by Surgery

STUDY ID: NCT00575770

**STUDY PURPOSE:** Immunotoxins can find tumor cells and kill them without harming normal cells. Drugs used in chemotherapy, such as pemetrexed and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) together with immunotoxin therapy may kill more malignant mesothelioma cells. This phase I trial is studying the side effects and best dose of immunotoxin therapy when given together with pemetrexed and cisplatin in treating patients with malignant pleural mesothelioma that cannot be removed by surgery.

**STUDY TYPE:** Interventional

**STUDY CONTACT:** Raffit Hassan, MD. Warren Grant Magnuson Clinical Center, NCI Clinical Trials Referral Office; Bethesda, MD 20892. Tel. 888-NCI-1937.

## Dendritic Cell-based Immunotherapy Combined with Low-dose Cyclophosphamide in Patients with Malignant Mesothelioma

STUDY ID: NCT01241682

**STUDY PURPOSE:** Earlier the investigators determined the safety and feasibility of tumor lysate-pulsed dendritic cells as therapeutic adjuvants in mesothelioma patients. Because pre-clinical data in mice had shown that better results were obtained when regulatory T cells were depleted using low-dosis of cyclophosphamide, ten patients who responded on chemotherapy are selected for DC-treatment in combination with Endoxan.

**STUDY TYPE:** Interventional

**STUDY CONTACT:** Joachim Aerts, MD, PhD. Erasmus Medical Center; Rotterdam, Zuid-Holland, Netherlands, 3000 CA. Tel. +31-10-7043697.



## Bortezomib in Treating Patients with Malignant Pleural Mesothelioma

STUDY ID: NCT00513877

STUDY PURPOSE: Bortezomib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. This phase II trial is studying the side effects of bortezomib and how well it works in treating patients with malignant pleural mesothelioma.

STUDY TYPE: Interventional

STUDY CONTACT: Dean A. Fennell, MD, PhD. Centre for Cancer Research and Cell Biology at Queen's University Belfast; Belfast, Northern Ireland, UK BT9 7BL. Tel. +44-28-9097-2960.

## Axitinib in Malignant Mesothelioma

STUDY ID: NCT01211275

STUDY PURPOSE: The purpose of this study is to investigate the effects of axitinib, a potent angiogenesis inhibitor, on tissue and clinical outcome in combination with chemotherapy given to patients with mesothelioma.

STUDY TYPE: Interventional

STUDY CONTACT: Dr. P. Baas. Antoni van Leeuwenhoekziekenhuis (NKI-AVL); Amsterdam, Noord-Holland, Netherlands 1066 CX. Tel. +31-0-20-5122958.

## Pilot Study of Bisphosphonate Therapy (Zoledronic Acid) in Patients with Malignant Mesothelioma

STUDY ID: NCT01204203

STUDY PURPOSE: The primary objective of this trial is to determine the response rate of single agent zoledronic acid using a composite of criteria including the EORTC modified RECIST criteria and the EORTC tumor response criteria for 18F-FDG PET scans.

STUDY TYPE: Interventional

STUDY CONTACT: Francisco Robert, MD. University of Alabama at Birmingham; Birmingham, AL 35294. Tel. 205- 934-9999.

## FR901228 and Flavopiridol in Treating Patients With Advanced Lung, Esophageal, or Pleural Cancer

STUDY ID: NCT00098644

STUDY PURPOSE: Drugs used in chemotherapy, such as FR901228 and flavopiridol, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving FR901228 together with flavopiridol may kill more tumor cells. This



phase I trial is studying the side effects and best dose of FR901228 when given together with flavopiridol in treating patients with advanced lung, esophageal, or pleural cancer.

STUDY TYPE: Interventional

STUDY CONTACT: David S. Schrupp, MD. NCI - Center for Cancer Research; Bethesda, MD 20892. Tel. 888-NCI-1937.

## Pemetrexed Disodium and Cisplatin With or Without Cediranib Maleate in Treating Patients With Malignant Pleural Mesothelioma

STUDY ID: NCT01064648

STUDY PURPOSE: Drugs used in chemotherapy, pemetrexed disodium and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Cediranib maleate may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth and by blocking blood flow to the tumor. Giving pemetrexed disodium and cisplatin together with cediranib maleate may kill more tumor cells. This randomized phase I/II trial is studying the side effects and best dose of cediranib maleate when given together with pemetrexed disodium and cisplatin and to see how well it works in treating patients with malignant pleural mesothelioma.

STUDY TYPE: Interventional

STUDY CONTACT: Anne S. Tsao, MD. M. D. Anderson Cancer Center at University of Texas; Houston, TX 77030. Tel. 713-792-3245.

## AMG 102, Pemetrexed Disodium, and Cisplatin in Treating Patients with Malignant Pleural Mesothelioma

STUDY ID: NCT01105390

STUDY PURPOSE: Monoclonal antibodies, such as AMG 102, can block tumor growth in different ways. Some block the ability of tumor cells to grow or spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Drugs used in chemotherapy, such as pemetrexed disodium and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving AMG 102 together with pemetrexed disodium and cisplatin may kill more tumor cells. This phase II trial is studying how well giving AMG 102 together with pemetrexed disodium and cisplatin works in treating patients with malignant pleural mesothelioma.

STUDY TYPE: Interventional

STUDY CONTACT: James Stevenson, MD. Abramson Cancer Center of the University of Pennsylvania; Philadelphia, PA 19104. Tel. 215-662-8628.



## Pemetrexed Disodium and Cisplatin Followed by Surgery with or without Radiation Therapy in Treating Patients with Malignant Pleural Mesothelioma

STUDY ID: NCT00334594

**STUDY PURPOSE:** Drugs used in chemotherapy, such as pemetrexed disodium and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving chemotherapy before surgery may make the tumor smaller and reduce the amount of normal tissue that needs to be removed. Radiation therapy uses high-energy x-rays to kill tumor cells. Giving radiation therapy after surgery may kill any tumor cells that remain after surgery. This randomized phase II trial is studying how well giving pemetrexed disodium together with cisplatin followed by surgery with or without radiation therapy works in treating patients with malignant pleural mesothelioma.

**STUDY TYPE:** Interventional

**STUDY CONTACT:** Rolf A. Stahel, MD. UniversitaetsSpital Zuerich; Zurich, Switzerland CH-8091. Tel. +41-1-634-2871.

## Study of Patients with Non-Small Cell Lung Cancer, Esophageal Cancer, Malignant Pleural Mesothelioma, Mediastinal or Chest Wall Neoplasms, or Lung Metastases from Cancers of Non-Thoracic Origin

STUDY ID: NCT00447447

**STUDY PURPOSE:** Collecting and storing samples of tissue, blood, and urine from patients with cancer to study in the laboratory may help the study of cancer. It may also help doctors identify patients who are eligible for clinical trials. This study is collecting and examining tissue, blood, and urine samples from patients with non-small cell lung cancer, esophageal cancer, malignant pleural mesothelioma, mediastinal or chest wall neoplasms, or lung metastases from cancers of non-thoracic origin.

**STUDY TYPE:** Interventional

**STUDY CONTACT:** David S. Schrupp, MD. Warren Grant Magnuson Clinical Center, NCI Clinical Trials Referral Office; Bethesda, MD 20892. Tel. 888-NCI-1937.

## Biomarkers to Detect Mesothelioma Early in Patients Exposed to Asbestos or Vermiculite

STUDY ID: NCT00897247

**STUDY PURPOSE:** Studying samples of body fluid and blood from patients who have been exposed to asbestos or vermiculite in the laboratory may help doctors learn more about changes that may occur in DNA and identify biomarkers related to cancer. This laboratory study is looking for biomarkers to detect mesothelioma early in patients exposed to asbestos or vermiculite.

**STUDY TYPE:** Interventional



STUDY CONTACT: Anil Wali, PhD. Barbara Ann Karmanos Cancer Institute; Detroit, MI 48201. Tel. 313-576-9363.

## Mesothelin and Osteopontin as Diagnostic Markers in Patients with Mesothelioma or Atypical Mesothelial Hyperplasia

STUDY ID: NCT00899613

STUDY PURPOSE: Studying levels of mesothelin and osteopontin in samples of blood from patients with mesothelioma or atypical mesothelial hyperplasia may help doctors identify biomarkers related to cancer. This research study is looking at mesothelin and osteopontin as diagnostic markers in patients with mesothelioma or atypical hyperplasia.

STUDY TYPE: Interventional

STUDY CONTACT: Francoise Galateau-Salle. University Hospital, Caen; Caen, France 14033. Tel. 33-231-064-923.

## Pemetrexed Disodium or Observation in Treating Patients with Malignant Pleural Mesothelioma without Progressive Disease After First-Line Chemotherapy

STUDY ID: NCT01085630

STUDY PURPOSE: Pemetrexed disodium may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. This randomized phase II trial is studying how well pemetrexed disodium or observation works in treating patients with malignant pleural mesothelioma without progressive disease after first-line chemotherapy.

STUDY TYPE: Interventional

STUDY CONTACT: Arkadiusz Dudek, MD. Masonic Cancer Center, University of Minnesota; Minneapolis, MN 55455. Tel. 612-624-2620.

## Anti-TGF Monoclonal Antibody (GC1008) in Relapsed Malignant Pleural Mesothelioma

STUDY ID: NCT01112293

STUDY PURPOSE: This study is being conducted to evaluate the overall safety and effectiveness of an investigational drug, GC1008, in patients with mesothelioma. An investigational drug is one that has not been approved by the FDA. Approximately 40 people will be enrolled on this study at the University of Pennsylvania (Main Institution/Coordinating Site) and the University of Chicago (Participating Institution). We expect about 20 subjects to be enrolled at each institution.



STUDY TYPE: Interventional

STUDY CONTACT: Mona Jacobs-Small. Abramson Cancer Center of the University of Pennsylvania; Philadelphia, PA 19104. Tel. 215-662-8632.

## Quality of Life and Survivorship Care in Patients Undergoing Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (HOPE)

STUDY ID: NCT01126346

STUDY PURPOSE: An orientation and patient education program and telephone counseling may help improve the quality of life in patients with peritoneal surface malignancies. This clinical trial studies quality of life and survivorship care in patients undergoing surgery and chemotherapy for peritoneal surface malignancies.

STUDY TYPE: Interventional

STUDY CONTACT: Richard McQuellon. Wake Forest University Health Sciences; Winston-Salem, NC 27157. Tel. 336-716-7980.

## Phase I Dose-Escalation Study of Azacitidine In Combination With Temozolomide

STUDY ID: NCT00629343

STUDY PURPOSE: The purpose of this study is to determine safety and toxicity for the combination of Temozolomide and Azacitidine in the treatment of Advanced Soft Tissue Sarcoma or Malignant Mesothelioma. This is a single-center, open-label, single-arm Phase I dose-escalation trial. Patients will be evaluated with complete history and physical as well as laboratory studies (complete blood count, metabolic panel, liver function tests), biopsy, and imaging of all sites of measurable disease. This study will be conducted over the course of 3 years.

STUDY TYPE: Interventional

STUDY CONTACT: Danielle Banks. Columbia University Medical Center; New York, NY 10032. Tel. 212-305-3846.

## A Study of Cetuximab Combined With Cisplatin or Carboplatin/Pemetrexed as First Line Treatment in Patients With Malignant Pleural Mesothelioma

STUDY ID: NCT00996567

STUDY PURPOSE: Multicenter, open phase 2 study on patients with malignant mesothelioma. Standardly, 4 to 6 cycles of palliative chemotherapy, platinum in combination with pemetrexed, are given. Despite of this treatment, median survival is poor (9-12 months). By combining



conventional cytotoxic agents with a novel agent, hopefully treatment and survival can be approved. Cetuximab or Erbitux is a monoclonal antibody against the EGFR (Epidermal Growth Factor Receptor). By blocking the receptor, it interferes with cell growth and division. Most mesothelioma show a strong expression of the EGFR protein. Apart from that, Cetuximab also has antibody-dependent cell-mediated cytotoxicity (ADCC).

In this trial, patients will be treated with standard chemotherapy, combined with Cetuximab weekly. After a maximum of 6 cycles of chemotherapy, administration of Cetuximab will be continued until disease progression. Every 6 weeks, a CT scan will be done to evaluate therapy. Most common side effect of Cetuximab is acneiform rash.

The translation research program consists of the determination of EGFR- and K-Ras mutations on the tumor tissue and the correlation with outcome.

In the first part of the trial, 18 patients will be included. After a positive interim analysis, a total of 43 patients will be included.

STUDY TYPE: Interventional

STUDY CONTACT: Veerle Surmont, MD. University Hospital Ghent; Ghent, Belgium 9000. Tel. +32-9-332-1530.

## N-AcetylCysteine vs. Placebo to Prevent Neurotoxicity Induced by Platinum Containing Chemotherapy (NAC-PNP)

STUDY ID: NCT00637624

STUDY PURPOSE: In this study we want to investigate the efficacy of N-acetylcysteine (NAC), which is an anti-oxidant, in the prevention of cisplatin-induced neural toxicity, in patients treated for lung cancer with chemotherapy containing cisplatin.

STUDY TYPE: Interventional

STUDY CONTACT: Idris Bahce, MD. Rijnstate Hospital; Arnhem, Gelderland, Netherlands 6800TA. Tel. +31-2-637-888-88 ext. 3652.

## Electronic Tool to Record Cancer Symptoms in Patients with Advanced Cancer Receiving Palliative Care

STUDY ID: NCT00477919

STUDY PURPOSE: A hand held electronic tool used to monitor symptoms and assess quality of life may improve communication between patients and their doctors and improve the ability to plan treatment for patients with advanced cancer receiving palliative care. It is not yet known whether symptoms are better controlled with or without use of this electronic tool. This randomized phase III trial is studying an electronic tool to see how well it records cancer symptoms in patients with advanced cancer receiving palliative care.

STUDY TYPE: Interventional

STUDY CONTACT: Florian Strasser, MD, ABHPM. Kantonsspital - St. Gallen; St. Gallen, Switzerland CH-9007. Tel. +41-71-494-1111.



## Collecting Tumor Samples from Patients with Gynecological Tumors

STUDY ID: NCT00897442

STUDY PURPOSE: Collecting and storing samples of tumor tissue and blood from patients with cancer to study in the laboratory may help in the study of cancer. This laboratory study is collecting tumor tissue and blood samples from patients with gynecologic tumors.

STUDY TYPE: Interventional

STUDY CONTACT: Michael L. Cibull, MD. Lucille P. Markey Cancer Center at University of Kentucky; Lexington, KY 40536. Tel. 859-257-3379.

## Everolimus (RAD001) for the Treatment of Malignant Pleural Mesothelioma With Merlin/NF2 Loss as a Biomarker to Predict Sensitivity

STUDY ID: NCT01024946

STUDY PURPOSE: For patients with malignant pleural mesothelioma that has grown despite treatment with standard chemotherapy, no treatment has yet proven beneficial. The purpose of this study is to find out what effects, both good and bad, that everolimus has on the cancer. Everolimus works by blocking a protein that helps the cancer grow. The goal of this clinical research study is to learn if the study drug everolimus can shrink or slow the growth of mesothelioma. The safety of this drug will also be studied. The patients' physical state, changes in the size of the tumor, and laboratory findings taken during the study will help us decide if everolimus is safe and effective.

STUDY TYPE: Interventional

STUDY CONTACT: Lee Krug, MD. Memorial Sloan-Kettering Cancer Center; New York, NY 10065. Tel. 212-639-8420.

## Radical Pleurectomy/Decortication (PD) and Intensity Modulated Radiotherapy (IMRT)

STUDY ID: NCT01134146

STUDY PURPOSE: The goal of this clinical research study is to find the highest tolerable dose of radiation that can be given to directly to the pleura (the outer lining of the lungs) using intensity modulated radiation therapy (IMRT) in patients with malignant mesothelioma (MM) who have had a pleurectomy.

STUDY TYPE: Interventional

STUDY CONTACT: Daniel Gomez, MD. UT MD Anderson Cancer Center; Houston, TX 77030. Tel. 713-563-2300.



## Early Diagnosis of Lung Cancer and Mesothelioma in Prior Asbestos Workers

STUDY ID: NCT00188890

**STUDY PURPOSE:** Occupational exposure to asbestos is known increase the risk of developing cancer of the lungs (bronchogenic carcinoma) or of the pleura (mesothelioma). Symptoms are subtle and non-specific, diagnosis is often late and the prognosis consequently is dismal. Currently there is no accepted non-invasive tool for the early diagnosis of mesothelioma or lung cancer in asbestos-exposed subjects. In the last decade, low-dose computed tomography (LDCT) has been successfully developed and validated for the early diagnosis of lung cancer in high-risk smokers. Malignant mesothelioma might, in an early stage, resemble a benign pleural plaque, which is a common finding after asbestos exposure. We target to develop low-dose CT as a tool to serially image the pleural plaques, quantify their individual and overall volume, compute the growth rate with time, and, as such, identify the presence of mesothelioma early, before symptoms occur.

**STUDY TYPE:** Interventional

**STUDY CONTACT:** Demetris Patsios, MD. Princess Margaret Hospital - University Health Network, Toronto; Toronto, Ontario, Canada. Tel: 416-603-5800 ext. 2583.

## Disclaimer

The selection of a physician, treatment center, or course of treatment is an important and personal matter. It should be made by the patient and his/her family in consultation with the patient's healthcare providers. The above information is provided as an informational resource by Seeger Weiss LLP to assist in the exploration of these options with a qualified healthcare representative and is subjective to the disclaimer at [www.mesotheliomasymptoms.com/disclaimer](http://www.mesotheliomasymptoms.com/disclaimer). Seeger Weiss LLP does not itself endorse any physician or treatment option.