

THE CLINICAL CANCER LETTER

Cancer research news for clinicians

Lung Cancer Screening

ACCP and ASCO Publish Joint Guideline Following Review of Evidence on Low-Dose CT

The American College of Chest Physicians and the American Society of Clinical Oncology updated their guidelines on the role of CT screening for lung cancer.

An expert panel led a joint systematic review of lung cancer screening data and developed new clinical practice guideline recommendations, which addressed CT screening for current and former smokers who are at a high risk for lung cancer. The guidance was published in the Journal of the American Medical Association.

Several organizations took part in the review process, including ACCP, ASCO, the National Comprehensive Cancer Network and the American Cancer Society, with input from the American Thoracic Society. The review formed the basis of the clinical practice guidelines published by ACCP and ASCO, and was endorsed by ATS. Currently, ACS is developing a full lung cancer screening guideline of its own.

Specifically, the guideline recommends that smokers aged 55 to 74 who have smoked 30 pack/years or more should be offered annual screening with low-dose CT, instead of annual screening with chest lithograph or no screening. This includes current smokers or those who have quit within 15 years.

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Colorectal Cancer

NIH Study Finds Sigmoidoscopy Reduces Colon Cancer Incidence and Mortality Rates

In a study that spanned almost 20 years, researchers found that overall colorectal cancer mortality was reduced by 26 percent and incidence was reduced by 21 percent as a result of screening with flexible sigmoidoscopy.

The research, sponsored by NCI, appeared online in the New England Journal of Medicine and was presented at Digestive Disease Week, a scientific conference.

Previous research has shown that colorectal cancer incidence and mortality can be reduced with a number of screening methods, including fecal occult blood testing. However, flexible sigmoidoscopy and colonoscopy are more sensitive than FOBT for detecting polyps that may lead to colorectal cancer.

“The most important message is that, regardless of modality chosen, colorectal cancer screening lowers mortality from colorectal cancer, and all individuals 50 and over should be screened,” said study author Christine

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Joint Guideline Defines High Risk Lung Cancer Population

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The guideline recommends against performing annual CT screening on individuals who have accumulated fewer than 30 pack/years of smoking; are younger than 55, or older than 74; or who quit more than 15 years ago. The guideline also recommended against screening individuals with severe comorbidities that would preclude potentially curative treatment and/or limit life expectancy.

The panel analyzed 21 studies of low-dose CT screening. The most important was the National Lung Screening Trial, which studied 53,454 people with a smoking history of at least 30 pack/years. The study found that individuals who were screening with low-dose CT had a 20 percent lower chance of dying from lung cancer, compared to chest X-rays.

The trial demonstrated significantly less lung cancer mortality (median follow-up, 78 months; relative risk = 0.80%, 95% CI: 0.73 to 0.93; $p = 0.004$) and all-cause mortality (RR = 0.93%, 95% CI: 0.86-0.99, $p = 0.02$) with low-dose CT screening.

The guidelines recommend that the screening be carried out at centers that can offer the same comprehensive care that was received by the people enrolled in the NLST.

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Childhood Cancer

Crizotinib Eliminated Tumors In 7 of 8 Children with ALCL

Results from a phase I trial of crizotinib demonstrated that children and adolescents with anaplastic large cell lymphoma and neuroblastoma had their tumors disappear, even after standard treatment had failed.

Crizotinib (Xakori) blocks the activity of anaplastic lymphoma kinase proteins. It is approved by FDA for adults with with non-small cell lung cancer harboring ALK gene alterations.

ALK gene alterations are present in nearly all children with ALCL and in about 10 percent of children with neuroblastoma. ALK gene alterations also occur occasionally in other childhood cancers.

The multi-center trial, led by investigators from the Children's Oncology Group, included 70 participants, whose average age was 10 years (the patients ranged from 1 to 21 years of age). At admission, tumor tissue was tested for the presence of ALK gene alterations.

The investigators started the trial by providing dosages of crizotinib to their patients that were lower than those used in adults with NSCLC.

The children and adolescents in this trial took crizotinib by mouth twice a day for 28 days and were allowed to continue the drug longer if their disease did not progress and if there were no signs of unacceptable toxicity. The investigators were able to safely increase the crizotinib dose through six dose levels with minimal toxicity, to a dose that exceeds that used in adults.

The researchers monitored study participants for changes in their tumor size. Among the eight patients with ALCL enrolled, seven showed complete disappearance of their tumor.

Of the 27 patients with neuroblastoma, three have had complete responses (two are known to have an ALK mutation) and seven have had no disease progression. These patients have remained on therapy between nine months to more than two years without progression.

Seven patients with inflammatory myofibroblastic tumor, a rare form of sarcoma that commonly has ALK gene alterations, remain on therapy, with the majority showing benefit.

"There is a major opportunity to personalize therapy for children with neuroblastoma and anaplastic large cell lymphoma by providing a relatively non-toxic drug that may allow us to lower the doses of conventional chemotherapy in the very near future," said Yael Mosse, the study chair and an assistant professor

of pediatrics at The Children's Hospital of Philadelphia.

Results of the phase I trial were released by the American Society of Clinical Oncology. The study was presented at the ASCO 2012 meeting in Chicago. COG is developing additional studies in which crizotinib will be combined with chemotherapy in patients with ALCL and neuroblastoma.

Colorectal Cancer **Twenty-Year NIH Study Finds Sigmoidoscopy Reduces Mortality**

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Berg, chief of NCI's Early Detection Research Group and project officer of the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial.

From 1993 to 2001, a total of 154,900 men and women aged 55 through 74 were randomly assigned to receive flexible sigmoidoscopy screening or usual care as part of the PLCO trial. People in the usual care group only received screening if they asked for it, or if their physician recommended it.

This large, population-based, randomized trial was designed to determine the effects of screening on cancer-related mortality.

Participants assigned to the flexible sigmoidoscopy group were screened once on entering the study and again three to five years later. The participants were followed for approximately 12 years to collect data on cancer diagnoses and deaths.

The researchers compared overall colorectal cancer mortality and incidence in the two groups, and also analyzed incidence and mortality according to the location of the cancers that developed. Cancers located from the rectum through a bend in the colon called the splenic flexure were defined as distal, and those in the transverse colon to the cecum were defined as proximal. Although flexible sigmoidoscopy examines only the rectum and sigmoid colon, participants with a suspicious finding were referred for a follow-up colonoscopy, in which both the distal and proximal regions of the colon would be examined.

Overall, after an average of nearly 12 years, participants in the screening group had a 21 percent lower incidence of colorectal cancer overall and a 26 percent lower rate of colorectal cancer mortality than participants in the usual care group.

This means that, over the course of 10 years, if 1,000 people followed the PLCO protocol of two sigmoidoscopy screenings, there would be

approximately three fewer new cases and one fewer death from colorectal cancer than in a comparable group not receiving regular screenings.

The incidence of distal colorectal cancer was reduced by 29 percent, and mortality from distal colorectal cancer was reduced by 50 percent, in the screening group. While there was no statistically significant decline in deaths from proximal colorectal cancer, the incidence of proximal colorectal cancer was reduced by 14 percent in the screening group.

"This is the second major trial that has shown that sigmoidoscopy is effective in reducing the risk of dying of colorectal cancer. Sigmoidoscopy is less invasive than colonoscopy and carries a lower risk of the colon being perforated, which may make it more acceptable as a screening test to some patients," said Barnett Kramer, director of NCI's Division of Cancer Prevention. "There are several effective screening tests for colorectal cancer, and the most effective screening test is the one that people choose to take."

Screening by sigmoidoscopy detected 24 percent of the colorectal cancers that were diagnosed in the screening group. Another 60 percent were detected by symptoms or by screening performed outside of the PLCO protocol or were found more than one year after a screening exam—the cutoff for defining a cancer as screen detected—in participants who had at least one screening exam, and the remaining 16 percent developed in participants assigned to the screening group who never actually underwent screening.

Of the colorectal cancers that were detected by screening, nearly 83 percent were found in the distal colon, whereas distal colorectal cancers made up about 53 percent of the cancers in people in the screening group who were never screened and about 32 percent of cancers in people who underwent screening but whose cancers were not detected by screening.

Cancers detected by screening were more likely to be early stage (75 percent were stage I or II) than cancers that weren't detected by screening (51 percent were stage I or II). Screening was associated with reductions in incidence and mortality for all stages of distal colorectal cancer. However, in the proximal colon, reductions in incidence were only seen in stages I, II, and III, and there was no impact on proximal colorectal cancer mortality.

The researchers estimated that if they had used colonoscopy rather than sigmoidoscopy in this study, they would have identified 16 percent more cancers, two-thirds of which would have been proximal cancers.

However, they were not able to determine what

effect that may have had on proximal colorectal cancer mortality. There has been some controversy about how effective colonoscopy is in decreasing colorectal cancer mortality in different regions of the colon, with some studies suggesting that it is more effective against distal than proximal tumors. Sigmoidoscopy has never been directly compared to colonoscopy in a definitive clinical trial.

False-positive sigmoidoscopy results were observed in 20 percent of men and 13 percent of women in the screening group, but some of these false positives could have been the result of false-negative colonoscopies done to follow up on suspicious sigmoidoscopy findings.

Approximately 22 percent of people in the screening group were sent for follow-up colonoscopies during the screening phase of the trial.

Renal Cell Carcinoma

Tivozanib Trumps Sorafenib In 1st-Line Renal Cancer Study

Results from a phase III clinical trial evaluating tivozanib versus sorafenib in first-line advanced renal cell carcinoma showed that tivozanib produced a statistically significant difference in progression-free survival.

The study, TIVO-1, was presented at the 2012 Annual Meeting of the American Society of Clinical Oncology.

Tivozanib is a selective, long half-life inhibitor of all three vascular endothelial growth factor receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Tivozanib is sponsored by AVEO Oncology and Astellas Pharma Inc.

A total of 517 patients were randomized to tivozanib (n=260) or sorafenib (n=257). The performance status and other prognostic indicators of patients enrolled in this study were consistent with other trials in first-line advanced RCC.

Based on independent radiological reviews, tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib in the overall study population (HR=0.797, 95% CI 0.639–0.993; P=0.042).

The objective response rate for tivozanib was 33 percent compared to 23 percent for sorafenib (p=0.014). The efficacy advantage of tivozanib over sorafenib was consistent across subgroups in the study.

In patients who were treatment-naïve for advanced RCC (70 percent of total study population), tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median PFS of 9.1 months for sorafenib (HR 0.756, 95% CI 0.580–0.985; P=0.037). This is the longest median PFS reported to date in treatment-naïve advanced RCC patients in a pivotal study.

In the subpopulation of patients who were pretreated with systemic therapy including cytokines (30 percent of total study population), tivozanib demonstrated an improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib.

Study results demonstrated favorable tolerability as evidenced by a distinctively low rate of dose interruptions and reductions. The most common adverse event for tivozanib was hypertension and for sorafenib was hand-foot syndrome. Other adverse events included diarrhea, fatigue, and neutropenia.

The rate of dose interruptions due to adverse events was 18 percent for tivozanib compared to 35 percent for sorafenib (p<0.001). The rate of dose reductions was 14 percent for tivozanib compared to 44 percent for sorafenib (p<0.001).

The trial's overall survival data are not yet mature. In TIVO-1, 53 percent of patients randomized to the sorafenib arm of the trial went on to receive subsequent therapy, nearly all of whom received tivozanib after sorafenib.

Based on an interim analysis, 81 percent of these patients achieved one-year overall survival. In comparison, only 17 percent of patients randomized to tivozanib went on to receive a subsequent therapy, and 77 percent of these patients achieved one-year overall survival. Mature data are expected to be presented in 2013.

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Leukemia

Blinatumomab Shows Response In Adults with Refractory ALL

Results from a phase II study showed that treatment with blinatumomab demonstrated complete response in 72 percent of the study's adult patients with relapsed or refractory B-precursor acute lymphoblastic leukemia.

Blinatumomab is the first of a new class of agents called bi-specific T cell engager antibodies, designed to harness the body's cell-destroying T cells to kill cancer cells.

The drug targets cells expressing CD19, a protein found on the surface of B-cell derived leukemias and lymphomas, such as ALL. The modified antibodies are designed to engage two different targets simultaneously, thereby juxtaposing T cells to cancer cells.

In the single-arm, dose-ranging trial, 26 of the 36 patients treated with blinatumomab across all of the tested doses and schedules achieved a complete response with partial hematologic recovery. Full results of the study were presented during an oral abstract session at the 48th Annual Meeting of the American Society of Clinical Oncology on June 4.

Patients received blinatumomab for 28 days followed by two weeks off therapy over a six week treatment cycle, for up to five treatment cycles. Patients received a continuous intravenous infusion of blinatumomab at an initial dose of five or 15 micrograms per meter squared per day, ranging up to 30 micrograms for the remainder of the treatment.

The primary endpoint of the study was the rate of complete response with partial hematologic recovery. Secondary endpoints included molecular response rate, duration of response and overall survival.

All but two patients achieved a molecular response, meaning there was no evidence of leukemic cells by polymerase chain reaction. No treatment related deaths or serious adverse events were reported in the study.

At the time of the analysis, median survival was 9.0 (8.2, 15.8) months with a median follow-up period of 10.7 months. In the group of patients who received the selected dose, median survival was 8.5 months. The median duration of response in the 26 patients who responded to treatment was 8.9 months.

For patients who received the selected dose and schedule, the most common adverse events were grade one or two and included pyrexia, headache, tremor and fatigue. These were most frequently seen at the onset of treatment in cycle one. Reversible central nervous system events led to treatment interruptions in six

patients, with two patients permanently discontinuing treatment. Cytokine release syndrome led to treatment interruption in two patients.

Blinatumomab (AMG 103), sponsored by Amgen, received orphan drug designation from FDA for the treatment of ALL, chronic lymphocytic leukemia, hairy cell leukemia, prolymphocytic leukemia and indolent B cell lymphoma and from the European Medicines Agency for the treatment of indolent B cell lymphoma, ALL, CLL and mantle cell leukemia.

Multiple Myeloma

Lenalidomide Maintenance Increased PFS and Survival

Data from a study assessing lenalidomide as maintenance therapy for patients with multiple myeloma show that the drug significantly improved the time to progression and patients' overall survival.

Lenalidomide (Revlimid), when administered after induction therapy and hematopoietic stem-cell transplant, reduced patients' risk of disease progression to 20 percent, compared to 44 percent disease progression in the placebo arm.

Among 460 patients aged 18 to 70 (median age 59), 321 were randomly assigned to the lenalidomide arm, and 229 to the placebo group. All participants had received prior autologous hematopoietic stem-cell transplantation and had stable disease.

The participants' assignments and responses to date were unblinded in December 2009 when the primary endpoint of the study (time to disease progression) showed a statistically significant difference between the two study groups. After January 2010, 86 of 128 eligible patients crossed over from the placebo arm to the active arm.

The study was published in the *New England Journal of Medicine*.

The researchers found that the therapy extended the time to disease progression by 19 months overall, even with the majority of placebo patients without progression crossing over to lenalidomide.

When the study data was analyzed again in October 2011, at a median follow-up of 34 months, 37 percent of participants receiving lenalidomide had disease progression or had died, compared to 58 percent of those in the placebo group.

A benefit in overall survival was also seen in this study. At a median follow-up of 34 months, a total of 15 percent of patients who received lenalidomide and

23 percent of the patients receiving placebo had died.

There was an increase in second primary cancers among the lenalidomide-arm patients. When looking at both study groups, the cumulative incidence of a second primary cancer was higher among patients in the lenalidomide group than among patients in the placebo group, and the cumulative incidence of progressive disease and death were higher among patients in the placebo group than among patients in the lenalidomide group.

The treatment was fairly well-tolerated—particularly compared to other treatments for multiple myeloma, such as thalidomide. There was more hematologic toxicity, particularly neutropenia, in the lenalidomide group.

Breast Cancer

5-Day Strut-based Brachytherapy Produced Low Recurrence Rates

Breast brachytherapy with a strut-based applicator demonstrated to be a well-tolerated and effective treatment for early-stage breast cancer after a median follow-up of four years, according to a study. The five-day radiation therapy, a form of accelerated partial breast irradiation, follows lumpectomy surgery.

The research was presented as a scientific poster at the European Society for Radiotherapy & Oncology World Congress of Brachytherapy in Barcelona.

The cancer recurrence rate in the study was comparable to the recurrence rate reported in literature for whole-breast irradiation, which takes six weeks and is the traditional form of radiotherapy for early-stage breast cancer.

Fifty patients were treated at three different institutions with APBI using the Strut-Adjusted Volume Implant. The poster reports successful completion of treatment in all 50 cases with favorably low recurrence rates and minimal acute and late toxicities.

There were no symptomatic cases of seroma, fat necrosis, or breast asymmetry from radiation treatment. Rates of other side effects including fibrosis, breast pain and hyperpigmentation were reported to be low.

Patients were treated at UC San Diego Moores Cancer Center, Arizona Breast Cancer Specialists in Phoenix, and 21st Century Oncology in Fort Myers, Fla.

A second study presented at the Barcelona conference, on the dosimetry of a small strut-based APBI device (SAVI 6-1 Mini), showed that the device is an excellent solution for patients with smaller breasts. The

finding helps confirm the applicator's ability to make breast brachytherapy an option for more women.

The 38-month study of 72 patients, by researchers at Texas Oncology and North Texas Hospital, showed that the breast brachytherapy device, which is the smallest of its kind, allowed for precise targeting of radiation.

Strut-based brachytherapy delivers a shortened course of radiation therapy for early-stage breast cancer patients following lumpectomy surgery. The strut-based, open architecture design allows physicians to sculpt radiation based on patient-specific anatomy, which increases the number of women who can benefit from APBI.

Bone Metastases

Common Chemotherapy Fertilizes Marrow Before Tumors Take Root

Researchers found that administering cyclophosphamide before bone tumors took root actually fertilized the bone marrow, which enabled cancer cells to seed and grow more easily.

The findings provide insight as to why some cancers metastasize to bone, and could eventually result in new metastasis-prevention drugs, said principal investigator Laurie McCauley, professor in the Department of Periodontics and Oral Medicine at the University of Michigan School of Dentistry.

Researchers reversed the tumor-friendly effect of cyclophosphamide by inhibiting a cell-communicating protein in the bone marrow, CCL2. The paper, "Cyclophosphamide Creates a Receptive Microenvironment for Prostate Cancer Skeletal Metastasis," appears in the journal *Cancer Research*.

Researchers administered cyclophosphamide experimentally to manipulate the environment inside the bone marrow prior to exposing experimental tumors. Cyclophosphamide therapy is used in certain cancers to slow cell growth, and the researchers experimented with its use in a pre-metastatic mode using a prostate cancer model.

While effective at combating tumors, a side effect of cyclophosphamide is that it suppresses certain bone marrow cells that help the immune system and increases the amount of some harmful cells. Researchers hypothesized correctly that the drug would make the bone marrow more tumor-friendly.

"This work is early and still at the pre-clinical level," said McCauley. "However, the biggest potential

impact is in metastasis-preventive strategies.

“If we better understood the specific mediators, or conditions, in the bone marrow that support tumors, we could develop more effective therapeutics to prevent local cancers from spreading and hence reduce metastasis to the bone.”

Non-Hodgkin Lymphoma **Study Identifies Characteristics That Promote Early-Life NHL**

Family characteristics, high fetal growth, older maternal age, low birth order and male gender can all influence early life non-Hodgkin lymphoma incidence, according to a study.

Incidence of this disease has increased substantially over the past 50 years. Overall incidence in adults began to stabilize in the 1990s, but incidence has continued to climb in children and adolescents.

Perinatal factors have been thought to increase NHL risk, but previous studies of those factors were limited due to small sample sizes, wide variability in adjustment for confounding, and possible selection bias such as socioeconomic circumstances.

Researchers conducted a national cohort study of more than 3.5 million people born in Sweden from 1973 to 2008, and were followed for NHL incidence through 2009. The results of the study were published in JNCI.

Information on perinatal and family characteristics and NHL diagnoses were attained through linkage of national birth and cancer registries, and Cox proportional hazard models were used to assess association of those characteristics with the risk of NHL.

The researchers found that genetics and in utero conditions contributed to the incidence of NHL in adolescents. The strongest link was a family history of NHL in either a sibling or parent.

A high fetal growth rate, older maternal age, and low birth order also played a key role in incidence rates. Male gender was linked with NHL incidence in children younger than age 15, but not with later onset of NHL.

“These findings suggest several heterogeneous mechanisms including possible growth factor pathways in utero, immunologic effects of delayed infectious exposures, as well as other unmeasured environmental and genetic factors,” the authors wrote. “Further elucidation of these risk factors may facilitate the identification of high-risk individuals at young ages and potentially enable earlier detection and treatment.”

In an accompanying editorial, William Anderson

and Benjamin Emmanuel, of the NCI Division of Cancer Epidemiology and Genetics, wrote that this is a “well-performed national cohort study,” but point out certain limitations, including: the unavailability of host and environmental risk factors such as radiation and environmental contaminants. They also point out the small number of case patients.

However, they concluded that the study’s “large-scale and population-based design minimized selection bias and maximized generalizable conclusions for associations between NHL in early life and family history, high fetal growth weight, older maternal age, low birth order, and male sex.”

Survivorship **Study Links Exercise and Survival In Breast and Colon Cancer Mortality**

A study showed that physical activity is associated with reduced breast and colon cancer mortality. Evidence is insufficient to demonstrate association for other cancer types.

The study was published in JNCI.

To examine the association between physical activity and cancer survival, Rachel Ballard-Barbash, of the Applied Research Program in the Division of Cancer Control and Population Sciences at NCI and her colleagues reviewed 45 articles reporting both observational studies and randomized controlled trials that looked at the relationship between physical activity and mortality and/or cancer biomarkers among cancer survivors. The studies were published between January 1950 and August 2011.

The researchers found that the RCTs with biomarker endpoints suggest that exercise may provide benefits to survivors’ insulin levels, reduce inflammation, and possibly improve immunity.

The strongest evidence is for breast cancer survivors: most studies showed a statistically significant reduced risk of breast cancer and all-cause mortality associated with exercise. The next strongest evidence was for colorectal cancer survivors.

The authors point out that because of the diversity of the studies, it would be impossible to extrapolate specific recommendations on type and timing of physical activity. However, they can attest to the overall safety, physical and mental benefits of exercise for cancer survivors.

They add that future RCTs should look at different types of exercise, as well as how obesity, weight

loss, and cancer treatments may influence the effects of exercise on biomarkers. Also, how exercise may influence comorbidities in cancer survivors should be studied, they wrote.

Trials Approved by NCI CTEP For the Month of May

The National Cancer Institute Cancer Therapy Evaluation Program approved the following clinical research studies last month. For further information, contact the principal investigator listed.

Phase II

8993: A Randomized Phase II Study of Gemcitabine, Cisplatin Veliparib in Patients with Pancreas Adenocarcinoma and a Known BRCA/PALB2 Mutation (Part I) and a Phase II Single Arm Study of Single-Agent Veliparib in Previously Treated Pancreas Adenocarcinoma (Part II). Memorial Sloan Kettering Cancer Center; O'Reilly, Eileen M. (212) 639-6672

9111: A Phase 2 Study of Vorinostat (NSC 701852) in Metastatic Uveal Melanoma. Memorial Sloan Kettering Cancer Center; Carvajal, Richard D. (646) 888-4161

9177: Phase II Study of Dose-Adjusted EPOCH Rituximab in Adults with Untreated Burkitt Lymphoma, C-Myc Positive Diffuse Large B-Cell Lymphoma and Plasmablastic Lymphoma. National Cancer Institute Metabolism Branch; Dunleavy, Kieron Michael. (301) 435-1007

AMC-081: Feasibility Study of Safety, Toxicity, and Compliance of Concomitant Chemoradiotherapy for HIV-Associated Locally-Advanced Cervical Cancer. AIDS-Associated Malignancies Clinical Trials Consortium; Einstein, Mark H. (718) 405-8082

GOG-0279: A Phase II Trial Evaluating Cisplatin (NSC #119875) and Gemcitabine (NSC #613327) Concurrent with Intensity-Modulated Radiation Therapy (IMRT) in the Treatment of Locally Advanced Squamous Cell Carcinoma of the Vulva. Gynecologic Oncology Group; Horowitz, Neil Stuart. (617) 732-8843

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Phase II/III

ANHL1131: Intergroup Trial for Children or Adolescents with B-Cell NHL or B-AL: Evaluation of Rituximab Efficacy and Safety in High Risk Patients. Children's Oncology Group; Gross, Thomas Gene. (614) 722-3515

Phase III

S1202: A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer. Southwest Oncology Group; Henry, Norah Lynn (734) 936-4991

Other Phases

AALL12B5: Metabolic Pathways in T-Cell Acute Lymphoblastic Leukemia (T-ALL). Children's Oncology Group; Rathmell, Jeffrey C. (919) 681-1084

AAML12B8: Development of Pediatric Acute Myeloid Leukemia Xenograft Models for the Testing of Targeted Therapeutic Agents. Children's Oncology Group; Tasian, Sarah Kathleen. (215) 590-5476

ABTR12B3: Expression and Subcellular Localization of NEIL3 in Tumors. Children's Oncology Group; El-Hodiri, Heithem M. (614) 722-2868

ANBL12B7: Prognostic Impact of Segmental Chromosome Aberrations in Non MYCN Amplified Neuroblastomas in Different Age Groups. Children's Oncology Group; Ambros, Peter F. 1-40470-4050

ANBL12B7: Prognostic Impact of Segmental Chromosome Aberrations in Non MYCN Amplified Neuroblastomas in Different Age Groups. Children's Oncology Group; Ambros, Peter F. 1-40470-4050

AREN11B3: Validation of Copy Number Changes by MLPA as Predictors of Relapse in Wilms Tumor. Children's Oncology Group; Perlman, Elizabeth Jones. (773)880-4306

AREN12B6: Investigating the Frequency of Loss of Imprinting Across a Birth Cohort and the Link DNA Methylation Plays. Children's Oncology Group; Michels, Karin. (617) 732-8496

ARST12B3: Study Recurrency Testing of Mutations Identified in WGS of Pediatric Rhabdomyosarcoma. Children's Oncology Group; Pappo, Alberto S. 901-595-6765