Research Highlights

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Clinical Research

New Breast Cancer Drug Shrinks Tumors or Slows Growth in as Many as Half of Women

Breast cancer affects women of all ages at various stages in their lives. A new cancer drug has shown promising results. In a national phase I clinical trial at Duke Comprehensive Cancer Center in Durham, NC, lapatinib inhibited tumor growth in nearly half of the women who took it for eight weeks. Researchers presented data that revealed that 46% of patients with breast cancer who took lapatinib for eight weeks and 24% of patients who took the drug for four months had stable disease or tumor shrinkage. The results from using this cancer drug are encouraging. Lapatinib is one of the first drugs to elicit a response in women whose tumors did not respond to at least two traditional therapies, including trastuzumab (Herceptin®, Genentech, Inc., South San Francisco, CA). Lapatinib represents a new therapy because it targets HER-2 and epidermal growth factor. Blocking the action of two growth factors has a more profound effect on inhibiting cell growth.

When Combining New Oral Anticancer Agents With Standard Chemotherapy, Timing May Be Crucial

Timing is crucial when combining new generational oral molecularly targeted anticancer agents with standard chemotherapy drugs. University of California (UC) Davis Cancer Center researchers tested this notion and focused on a new oral epidermal growth factor receptor inhibitor known as erlotinib. Recent large-scale clinical trials compared the use of standard chemotherapy and erlotinib in the treatment of non-small cell lung cancer. The UC Davis Cancer Center team tested erlotinib alone, the standard chemotherapy agent docetaxel alone, erlotinib and docetaxel simultaneously, and the drugs sequentially. Docetaxel is the standard first-line chemotherapy drug for non-small cell lung cancer. Erlotinib works by blocking certain signals that cancer cells need to reach mitosis. The team predicted that giving docetaxel first and then erlotinib would be more effective than giving erlotinib first, giving the drugs alone, or giving both drugs simultaneously. The prediction proved to be true. One of the researchers theorized that when erlotinib is given simultaneously or immediately before docetaxel, fewer cancer cells reach cell division of mitosis and are more vulnerable to chemotherapy. A phase I trial of docetaxel followed by erlotinib in patients with non-small lung cancer is under way.

All Patients With Anorexia Receiving AVR118 Regained Appetite

A total of 25 patients with cancer cachexia or AIDS wasting was enrolled in phase I and II clinical trials in Israel. Ten patients with advanced AIDS and two patients with advanced pancreatic cancer received AVR118 (Advanced Viral Research Corp., Yonkers, NY) subcutaneously at a dose of 0.4 ml per day for 28 days (six days per week). Eight patients with AIDS received a dose of 2.0 ml per day and five patients received 4.0 ml per day on the same schedule. All patients were followed for 28 days after treatment was completed. Total weight, body mass index, fat percentage, strength, calf and arm circumference, and skin fold were measured for all patients with AIDS. All dose groups showed an increase in weight, strength, and fat percentage, with more significant improvement at the two higher dose levels. All patients with anorexia at entry became anorexia free after three weeks of therapy. About half of the patients also reported an improvement in their mood and increased daily activities, and 80% reported decreased fatigue.

Highlights of Three Studies Presented on Darbepoetin Alfa for Anemia

Patients suffering from cancer can experience anemia caused by the cancer itself or by treatment (e.g., chemotherapy). Treating this potentially serious anemia condition can be important not only to address the immediate problem but also to improve their quality of life and keep them on course with treatment. Aranesp® (darbepoetin alfa, Amgen Inc., Thousand Oaks, CA) has an increased potency and longer half-life and offers less frequent dosing than other options. The first study's results described how dosing Aranesp once every three weeks achieved and maintained the target hemoglobin levels recommended by clinical guidelines. This type of dosing could simplify the treatment of anemia. The second study presented an analysis of three identical, head-to-head trials showing that Aranesp dosed once every two weeks provided similar results as epoetin alfa dosed once every week in boosting hemoglobin and reducing the need of blood transfusions in patients with anemia. The last study demonstrated that Aranesp used in treating anemia in patients with cancer undergoing chemotherapy improves hemoglobin levels, reduces the need for transfusion, and improves fatigue experienced by patients.

Patients With Lung Cancer in Different Countries React Differently to the Same Chemotherapy Regimen

Two phase III clinical trials were conducted, one in the United States and another in Japan. This approach allowed researchers to make direct comparisons of the chemotherapy regimen—paclitaxel and carboplatin—for advanced non-small cell lung cancer in both populations. Patients in both trials were matched closely in terms of age, gender, disease stage, and tumor type. Median survival time was 12 months for Japanese patients versus 9 months for U.S. patients receiving the same regimen. Fifty-one percent of the Japanese subjects survived one year versus 37% of the American patients. The longer survival in the Japanese group was striking because the Japanese patients had to be given a lower dose of paclitaxel because of toxicity. Even with the lower dose, the Japanese patients were able to complete fewer cycles of the chemotherapy regimen and some side effects were more severe. Thus, this chemotherapy regimen appeared to be more effective, yet more toxic, in Japanese patients than in American patients. The reasons for these results remain unclear. The researchers hypothesized that the differences between the American and Japanese patients most likely resulted from genetic differences in drug metabolism, an area of science known as pharmacogenomics. This underscores the

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importance of genetic variations in medicine and points to a need for increased international collaboration.

Additional Research Highlights

Screening for Lung Cancer With Computed Tomography Has Not Proven Beneficial

An analysis of lung cancer screening studies was presented in the June 1, 2004, issue of the *Journal of Clinical Oncology*. Researchers at Duke University Medical Center and the Mayo Clinic devised a model to predict the lung cancer mortality rate among patients who had been screened using computed tomography (CT). They analyzed two major observational studies conducted to screen for lung cancer using CT scans and data from previously published five-year survival rates. Analysis of the CT studies estimated that 4.1–5.5 patients per 1,000 would die from lung cancer compared to the established lung cancer mortality rate of 3.0–4.4 deaths per 1,000 found in studies that do not use CT to screen patients. These data do not support that early diagnosis of a lung nodule will result in reduced mortality. Nearly 98% of all lung nodules detected on initial CT scans are not lung cancer. Second, analysis did not support the assumption that CT screening will reduce the incidence of late-stage tumors by detecting a higher percentage of tumors at an early stage. This is because finding a smaller tumor earlier does not mean that the tumor is at an earlier stage of cancer. It actually can represent late-stage cancer. The first randomized clinical study conducted is currently taking place nationwide at more than 40 sites to compare CT screening to chest x-rays. In the meantime, researchers at Duke University Medical Center are looking into identifying disease-causing proteins or biomarkers of the disease to help physicians diagnose the disease early.

Cervical Cancer Screening Is Effective in Reducing Mortality

A work group from the International Agency for Research on Cancer (IARC) concluded that cytologic screening programs can be effective in achieving an 80% reduction in mortality. Screening by cytologic examination of Pap test cell samples requires quality control measures of the entire process to be in place and active participation by women to achieve these results. Screening programs should include women aged 25–65 with screening completed once every three to five years until age 49 and then every five years. Advances in improved handling of cell samples and cytologic analysis with computers also could reduce mortality from cervical cancer. The IARC work group believes that sufficient evidence exists that the human papilloma virus (HPV) screening and vaccination can reduce mortality from cervical cancer. HPV accounts for more than 95% of all cervical cancer cases. Screening includes tests for the presence of viral DNA in a blood sample. The challenge will be to have an affordable, simple, and reliable test available for use around the world. Large-scale population-based research projects are in progress to validate low-cost tools that have high efficacy in reducing mortality from cervical cancer. A promising tool in low-resource countries is visual inspection of the cervix after application of acetic acid or iodine. Currently, the effects of this method of screening are unclear and efficacy is regarded as limited. Having tools and methods for cancer prevention available around the world is essential to be effective in reducing mortality. Ongoing research in the next few years will help to make low-cost, low-technology screening methods an option for countries that lack proper resources of their own.

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