

HealthyNEWS

August/September 2011

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Clinical Trials Help Patients Locally and Nationally

In partnership with Florida Gynecologic Oncology and the Gynecologic Oncology Group, known as GOG, Lee Memorial Health System’s Regional Cancer Center participates in clinical trials sponsored by the National Institutes of Health and National Cancer Institute. Many Southwest Florida women with gynecologic cancers—cervical, ovarian, uterine, vaginal, vulvar and endometrial—have participated in the GOG clinical trials.

“Most of the trials available at the Regional Cancer Center are Phase III studies that evaluate new drugs or a combination of drugs,” explains Alina Ward, Regional Cancer Center clinical research coordinator. “These studies are designed to compare the standard of care—drugs that are already approved for the type of cancer the participant has—to new drugs that have shown a clinical response in Phase I or II studies.”

Clinical trials are conducted in four phases. Each phase has a different purpose and helps scientists answer different questions.

- **Phase I** - researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range and identify side effects.
- **Phase II** - the experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
- **Phase III** - the experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the experimental drug or treatment to be used safely.
- **Phase IV** - post-marketing studies describe additional information, including the drug’s risks, benefits and optimal use.



All of the trials carried out at the Regional Cancer Center are part of national clinical trials, and are at Stage III or later. “By Stage III, we know the drug and dosage are safe,” Alina explains. “However, if our patients experience any serious side effects, we remove them from the trial and report this to the U.S. Food and Drug Administration.”

One study currently open evaluates the effect of chemotherapy on cognitive impairment, also known as “chemo brain”—a term commonly used to describe thinking and memory problems that can occur after chemotherapy treatments.

Participation in a clinical trial is voluntary, and participants can choose to stop at any time and for any reason. If you would like more information on clinical trials, please contact Alina Ward at 239-343-9547 or visit www.clinicaltrials.gov.