

Phase I Clinical Trials Benefit Patients With Aggressive Ovarian Cancer

Results of a study indicate that these trials can be good therapeutic options for people with heavily pretreated ovarian cancer.

June 13, 2019 By Taylor Abarca

Patients with recurrent, heavily pretreated ovarian cancer generally have few therapeutic options. Phase 1 clinical trials are considered by some providers as a “last hope.” Historically, there has been concern that there is little clinical benefit to these trials and high concern of toxicity, as these are typically first in human studies. However, these worries may be unnecessary. A University of Colorado Cancer Center study presented at the American Society of Clinical Oncology (ASCO) conference in Chicago indicates that there are therapeutic benefits for ovarian cancer patients that enroll in Phase 1 clinical trials.

“Historically there has been a concern that we only send patients with no clinical options left to these trials,” says Bradley Corr, MD, CU Cancer Center member and lead author on the study. “I don’t believe that to be true and advocate that these trials are often good therapeutic options, not just evaluations of safety and toxicity.”

The study looked at 132 patients with ovarian cancer that were treated in Phase 1 clinical trials from 2008 to 2018 at the CU Cancer Center. Treatment-related toxicities, patient characteristics, and survival data were assessed. The study found that:

- Patients were treated with an average of 5.5 chemotherapy lines before enrolling on a phase 1 trial
- 40 percent of the patients were treated on multiple Phase 1 clinical trials
- The median overall survival of the patients was 11.5 months
- No patients died due to treatment-related toxicity

“These results suggest that Phase I clinical trials for heavily pretreated ovarian cancer patients are safe by a standard of no patients experiencing toxicity-related deaths, which has been a concern in the medical community,” says Corr. “Based on the study I believe that Phase 1 clinical trial options should be considered for all heavily pretreated ovarian cancer patients if available to

them.”

About Ovarian Cancer

The American Cancer Society estimates that more than 22,000 women will be diagnosed with ovarian cancer and more than 13,000 will die from the disease in 2019. Ovarian cancer is often referred to as the “silent killer” because many patients don’t experience symptoms until the disease has advanced past the early stages.

Symptoms may include:

- Pain in abdomen or pelvis area
- Gastrointestinal discomforts such as nausea
- Abdominal fullness
- Back pain
- Increased abdominal girth
- Unexplained weight loss
- No symptoms at all

Currently there are no screening guidelines for ovarian cancer. Always contact your doctor if you have concerns.

What are clinical trials?

Clinical trials are a major part of medical care, treatment, and helping science move forward.

It is important to note that clinical trials do not pop out of thin air. Before a trial can start enrolling patients there are many steps that researchers and labs must take. Any new drugs/therapies go through a painstaking process of preclinical studies to show that they are likely safe and effective.

Once a new therapy/drug is approved (for more information about this process, click [here](#)), it moves on to a Phase 1 clinical trial. The goal of Phase 1 clinical trials is to test a drug’s safety. In this phase, doctors can also learn more about correct dosage, side effects, when and how often it should be taken, and how the cancer responds to the treatment. Typically, there are anywhere from 10 to 30 people in a Phase 1 clinical trial, which can last from months to a year.

Clinical trials allow doctors and researchers to test treatments that will extend lives and, increasingly, even lead to cures for some forms of the disease. Some patients will benefit from some clinical trials. Other patients understand that their involvement contributes to easing the burden of cancer for future patients.

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<http://beta.docker.realhealthmag.com/article/asco-phase-1-clinical-trials-benefit-patients-aggressive-ovarian-cancer>