

Safety of Antioxidants During GYN Cancer Care

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- *From:* J <studras@xxxxxxxx>
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<http://www.clinicaltrials.gov/ct/show/NCT00284427?order=10>

Safety of Antioxidants During GYN Cancer Care

This study is currently recruiting patients.
Verified by University of Kansas January 2006
Sponsored by: University of Kansas
Information provided by: University of Kansas
ClinicalTrials.gov Identifier: NCT00284427

Purpose

It is known that people with cancer are using antioxidant vitamins at high rates. It is not known if these vitamins are safe to use during cancer treatment. It is not known if common vitamins and minerals used by many cancer patients will interfere with cancer treatments by reducing the effectiveness of the cancer therapy. Preliminary studies that look at the addition of antioxidants during cancer therapy show us that antioxidants could play a significant role in the management of cancer.

Antioxidants are vitamins and other nutrients that help to decrease inflammation in the body by stopping free radicals or oxidants. Common antioxidants include vitamins E, C, and A, beta-carotene, and glutathione. Some doctors who treat cancer are now using antioxidants with chemotherapy while others believe they should not be used with cancer treatment.

The purpose of this study is to try and understand if it is safe efficacious to add antioxidant nutritional supplements to traditional chemotherapy and/or radiation therapy during the treatment of cancer.

Condition

Ovarian Cancer
Cervical Cancer
Uterine Cancer

Drug: Intravenous vitamin C (ascorbic acid)

Intervention Phase II

MedlinePlus related topics: Cervical Cancer; Ovarian Cancer; Uterine Cancer; Uterine Fibroids

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Study Type: Interventional

Study Design: Treatment, Non-Randomized, Historical Control, Single Group Assignment, Safety Study

Official Title: Safety of Oral Antioxidants and Intravenous Vitamin C During GYN Cancer Care

Further study details as provided by University of Kansas:

Primary Outcomes: Laboratory analysis, NCI Common Criteria for Toxicity version 3

Secondary Outcomes: Quality of life ? FACT-G at baseline, 6months, and completion

Expected Total Enrollment: 50

Study start: September 2005; Expected completion: December 2008

Last follow-up: December 2007; Data entry closure: December 2008

It is known that cancer patients use antioxidants at greater rates than their healthy peers and these patients generally do not tell their physicians. This use has not been adequately evaluated. This pilot trial is a Phase II study designed to assess safety of high-dose antioxidants in gynecologic malignancies. Secondarily, we will evaluate efficacy of antioxidant use. These goals will be accomplished by monitoring adverse events by clinical evaluation, metabolic functions such as but not limited to tumor markers, blood counts, hepatic, and renal enzymes, and tumor response rates secondarily. The study will be conducted at the University of Kansas Medical Center. Oversight partnership is established with the FDA-CDER, Kansas Masonic Cancer Research Institute, and the University of Kansas Medical Center ? IRB.

The study is an open label prospective investigational study in 50 gynecologic cancer patients with a Primary Hypothesis: To assess safety of adding high-dose antioxidants to chemotherapy in the treatment of gynecologic malignancies (uterine, cervical, or epithelial ovarian). Qualitative and quantitative toxicities will be assessed by monitoring clinical status by National Cancer Institute common toxicity criteria version 3.0, quality of life measures (FACT-G), and evaluating metabolic functions including but not limited to hepatic and renal function.

Secondary Hypothesis: To assess efficacy by tumor response rates in patients with gynecologic malignancies treated with antioxidants to include intravenous and oral ascorbic acid, intravenous glutathione, oral mixed carotenoids, mixed tocopherols, and vitamin A. Secondary endpoints will be time to progression and survival.

Patients with newly diagnosed or recurrent gynecologic cancer will be invited to participate and these subjects will be limited to those who present with cervical, uterine, or ovarian of epithelial origin. Fifty patients will be enrolled. The study subjects will be treated with antioxidants added to their usual oncologic care for 12 months. This population was chosen because of anecdotal and case report evidence for

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benefit when high-dose antioxidants are added to their care.

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It is anticipated that the results of this study will show safety when antioxidant therapies are added to chemotherapy in the treatment of gynecologic malignancies. It is unlikely that there will be interference of the chemotherapy by the antioxidants based on the experience of the Principal Investigator in a controlled trial and by anecdotal evidence. It is possible that there may be no benefit when antioxidants are added to cancer treatment. However, there may be improvements in quality of life (QOL) and we will be using the FACT–G, a validated QOL instrument to begin collecting preliminary data. We would like to begin collecting data in women with gynecologic malignancies who do not qualify for our current ongoing ovarian cancer trial. Data collected will be used in a future larger ROI submission.

Eligibility

Genders Eligible for Study: Female

Criteria

Inclusion:

* Patients must have histologically or cytologically diagnosed adenocarcinoma and/or sarcoma or squamous cell carcinoma of gynecologic origin (uterine, ovary, cervical) that is newly diagnosed or relapsed. Tumors of the ovary are restricted to epithelial origin. There must be evidence for advanced stage neoplasms and/or patients in need of

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chemotherapy for metastatic disease.

* The patient must be screened for eligibility and have care approved by treating oncologist; the oncology care is to be dictated by the oncology team.

* Patients must be of ambulatory status without evidence of active brain metastasis or spinal cord compression.

* ECOG Performance Status 0–2. (Grade 0 = Fully active, able to carry on all pre–disease activities without restriction Grade 1= Restricted in physical strenuous activity but ambulatory and able to carry out work of a light or sedentary nature e.g. light housework, office work Grade 2 = Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50% of waking hours.

* Laboratory: ANC =1,500/mm³, Hemoglobin > 8g/dL, platelet = 100,000/mm³, total bilirubin = 1.5 mg/dL, creatinine =2.0 mg/dL, transaminase (AST/ALT) =2.5X upper limit, urine uric acid < 1,000mg/d, urine pH <6, urine oxalate <60 mg/d.

* Willingness to take oral nutrients and answer FACT–G QOL questionnaires

* Patients who have no language barrier, are cooperative, and can give informed consent before entering the study after being informed of the medications and procedures to be used in this study may participate.

Exclusion:

* G–6PD deficient

* Ovarian tumors: sarcomas, germ cell, or any atypical cell line other than epithelial

* History of oxalate renal calculi; urine oxalate level > 60 mg/d at baseline

* History of bleeding disorder or hemochromatosis

* Patients undergoing radiation therapy

* Patients enrolled in other trials currently or in the preceding 3 month.

* Patients with evidence of a significant psychiatric disorder by history/examination that would prevent completion of the study will not be allowed to participate.

* ECOG Performance Status of 3–4. (Grade 3 = Capable of only limited self care, confined to bed or chair more than 50% of waking hours. Grade 4 = Completely disabled. Cannot carry on any self care. Totally confined to bed or chair.)

* Co–morbid condition that would affect survival: end stage congestive heart failure, unstable angina, myocardial infarction within 6 weeks of study, uncontrolled blood sugars = 300 mg/dL, patients with known chronic active hepatitis or cirrhosis.

* Patients who consume an excess of alcohol or abuse drugs (an excess of alcohol is defined as more than four of any one of the following per day: 30mL distilled spirits, 340mL beer, or 120mL wine) will not be allowed.

* Patients who smoke tobacco products will not be allowed to participate. Of note, patients who continue or begin to smoke are not allowed to continue with the protocol because we are unable to achieve

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elevation of the plasma vitamin C level to the desired 400 mg/dL. (Unless 400 mg/dL plasma level is achieved, there is no (presumed) chemotherapeutic action of the high-dose intravenous ascorbate) The inability to achieve the desired plasma level of ascorbate is presumably related to increased oxidative stress from the smoking itself. Patients will be clearly made aware of the possibility of coming off of protocol if they smoke. We will monitor cotinine levels (nicotine metabolite) in suspected smokers.

* Patients who are unwilling to take the oral antioxidants will not be allowed to participate.

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00284427

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Kansas

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More Information

Study ID Numbers: 10006

Last Updated: January 30, 2006

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