

Improving insulin resistance in gynecological cancer patients post-treatment using an integrative and functional medicine (IFM) food plan with and without cinnamon supplementation

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STUDY PROTOCOL

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Purpose of Study

The purpose of the study is to determine if the addition of cinnamon to a dietary intervention using an IFM food plan will be more effective in improving insulin resistance in post treatment gynecological cancer patients than using the food plan alone. The study results will be submitted to Dietitians in Integrative and Functional Medicine as an article in the newsletter and/or presented as a poster at the national conference. We intend to follow these patients long-term to determine if the food plan and any change in insulin sensitivity effects cancer recurrence.

Study Rational

Studies have shown that the supplementation with cinnamon in patients with type II diabetes and in patients with insulin resistance associated with polycystic ovarian syndrome can result in decreased mean fasting glucose, total available glucose, insulin levels, cholesterol levels and Hb A1c. Improvements were also noted in percentage body fat. Response rates were related to duration of the study, and the extent of obesity and glucose intolerance of the patient. The patients had to take the supplements for at least 24 weeks to see an effect.

Study Design

Participants will submit for the following blood draw tests: Oral Glucose Tolerance Test (OGTT) with insulins at baseline and week twenty-four. Participants in the supplement group will begin taking a supplement of cinnamon (cinnamon bark, 1700 mg/day) at week one and throughout the twenty-four weeks. Participants in the control group will take no supplement. All participants will begin the Integrative and Functional Medicine Cardiometabolic Food Plan (uses a modified Mediterranean approach with low glycemic impact) at week one and throughout the twenty-four weeks. Participants will meet with a registered dietitian during week one and fourteen for support with the food plan. Participants will self-monitor intake of food and nutrients, and complete weekly food logs for the dietitian to review.

The results of the lab tests will be collected as pre and post study data. Evaluation will include the following calculations derived from the OGTT: Insulin sensitivity index, HOMA-IR, Matsuda index, corrected early insulin secretory response (insulinogenic index/HOMA-IR and oral disposition index (product of Matsuda index and insulinogenic index. A mean glucose concentration will be calculated by looking at the serum values at 0 minutes, 30 minutes, 60 minutes and 120 minutes divided by 4. The mean glucose concentrations will be compared pre and post study in each arm and the pre and post study comparing arms. Liver enzymes will be checked on all participants eight weeks after starting the protocol and through cancer surveillance follow up. The following additional measurements will be taken at baseline and at 24 weeks:

Body fat determination using the Fit3D body scanner which is a noninvasive body scanner used to take measurements and a 3-dimensional view of the body, BMI calculation, and waist-hip ratio.



Study Objectives

Primary: To determine whether the addition of cinnamon to the implementation of an IF food plan will show a difference of 10 mg% in the mean glucose concentration measured when comparing the baseline and 24 week OGTT glucose levels.

Secondary: To determine whether the addition of cinnamon to the implementation of an IF food plan will improve weight loss, BMI, waist-hip ratio and glucose tolerance levels and related calculations more than just dietary intervention alone.

The Woman’s Hospital departments involved in the study include Gynecological Oncology to identify study participants, Health Information Management, Laboratory, Pharmacy for distribution of cinnamon supplements, and nutrition services Study Plan and Procedures.

Design

Prospective, randomized outpatient efficacy trial

Study Inclusion/Exclusion Criteria**Inclusion Criteria:**

Previously diagnosed with gynecological cancer and has completed all surgical intervention, chemotherapy, and/or radiation at least 3 months prior to enrollment but not greater than 24 months

Post-menopausal (absence of menstruation for > 1 year)

BMI > 25 but < 40

Exclusion Criteria:

No previous diagnosis of diabetes (HbA1c > 6.5%)

No other cancer diagnosis, excluding skin cancer

No chronic use of medication(s) interfering with glucose metabolism i.e. steroids, etc.

Consent of Subjects

Participation in the study is voluntary and participants may withdraw at any time by contacting the principal investigator. Signed consent gives Woman's Hospital the right to keep data for the time that the participant is being surveyed by Woman's gynecological oncology physicians. De-identified data may be used in publication.

Risk/Benefit to Study Participants

Allergic reaction to the cinnamon supplement may occur. Common symptoms of an allergic reaction include: nausea, stomach pain, diarrhea, vomiting, tingling/itching/swelling of face or other parts of the body, difficulty breathing, hives, dizziness, fainting, and rashes/inflammation/irritation or blistering of the skin.

Anaphylaxis is rare but can be potentially fatal and needs urgent medical attention. Symptoms include: sudden drop in blood pressure, difficulty breathing, loss of consciousness, and shock.

Blood draws may cause fainting, dizziness, and pain at injection site.

We anticipate that those who follow the food plan will lose an average of 5% of their body weight, and will improve their insulin sensitivity. We hope this food plan will decrease the risk of cancer recurrence. We hope this study will help cancer patients in the future. We will enroll 40 participants into this study.

Explanation of Statistics and Data Analysis

Sample size calculation was performed using the online calculator provided by the Massachusetts General Hospital Mallinckrodt General Clinical Research Center using a change of 10mg% in the mean glucose concentration as an endpoint. The sample size required would be 40 subjects, 20 in each arm.

Any statistics and data will be de-identified prior to presenting or publishing. Data will be kept within Woman's Hospital for any patient being monitored by Woman's Gynecological Oncology team.

How Records/Data will be Kept Confidential

Records and data from this study may include paper records that will be stored in a locked filing cabinet during the initial 6 months of the study and will be scanned into an electronic record and stored in a password protected electronic file thereafter as the patients are followed long-term by the gynecological oncology team. The participant's study records will be a part of their medical chart.

References:

Wambago et al. Do Cinnamon Supplements Have a Role in Glycemic Control in Type II Diabetes? A Narrative Review. *J Acad Nutr Diet*. 2016 Nov;116 (11): 1794-1802

Anderson RA. Chromium and polyphenols from cinnamon improve insulin sensitivity. *Proc Nutr Soc*. 2008 Feb; 67 (1): 48-53

Association of insulin resistance with breast, ovarian, endometrial and cervical cancers in non-diabetic women [Am J Cancer Res](#). 2016; 6(10): 2334–2344.