NRG-CC004

Phase II Double Blind Dose Finding Trial of Bupropion versus Placebo for Sexual Desire in Women with Breast or Gynecologic Cancer
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Schema

RANDOMIZATION

Women with breast or gynecologic cancer reporting low sexual desire

- Bupropion 150 mg XL in am daily x 8 weeks
- Bupropion 300 mg XL in am daily x 8 weeks
- Placebo in am daily x 8 weeks

Optional open label bupropion

Off study

Titration occurs from weeks 1 to 2
A total of 8 weeks at assigned dose
Outcome assessments at baseline, 2, 4, and 8 weeks
Two Step Registration

- Completion of questionnaires, eligibility criteria per PHQ-4 (<9) and FSFI desire subscale (<3.3)

- Then move to randomization including form with stratification questions
Eligibility Criteria

Prior to Step 1 Registration

• Score of <9 on the PHQ-4
• Patients must have FSFI desire subscale baseline score less than 3.3
• Diagnosis of breast or gynecologic cancer (all types)
• Completed definitive therapy consisting of surgery, chemotherapy, radiotherapy 180 days prior to registration
• Post-menopausal
• For breast cancer patients only, endocrine therapies are allowed (such as aromatase inhibitors, but not current tamoxifen. Prior tamoxifen is permitted with a 30 day wash out period).

See Section 3.0 of the Protocol for Complete Criteria
Eligibility Criteria

Prior to Step 2 Randomization
• Completion of the following baseline quality of life forms: PHQ4, FSFI, PROMIS sexual function and satisfaction, PROMIS fatigue short form 8a, Impact of Treatment Scale, PRO-CTCAE items, and Revised Dyadic Adjustment Scale. These quality of life forms will be required and data must be entered in RAVE at step 2 registration.

See Section 3.0 of the Protocol for Complete Criteria
Latest Amendment

• Clarified invasive BC and LCIS are allowed; added all types of gyne and BC allowed

• Clarified definition of postmenopausal; hopefully easier

• Added tamoxifen washout period

• 3.2.10 clarified use of antidepressants for mood and hot flashes versus major depression
Statistics

• Primary endpoint: Change in sexual desire, as measured by the desire subscale of the Female FSFI
• Target Accrual: 234 women
• Currently randomized 157 as of 4/30/2019
Patient Compliance

- 5 weeks (secondary)
  - 73% completed within timeframe
  - 19% completed out of time frame (+/- 7 days)
    - 7 completed > 7 days early
    - 18 completed > 7 days late
  - 10% not completed

- 9 weeks (primary)
  - 77% completed within timeframe
  - 10% completed out of time frame (+/- 7 days)
    - 4 completed > 7 days early
    - 10 completed > 14 days late
  - 13% not completed
**Important Reminders**

- Primary endpoint is a PRO; we need this data to answer the question or the study is for naught
  - Issues with data collection?
  - Issues with VisionTree?

- Study drug inhibits metabolism of certain other drugs so need to check this – enlist help of local pharmacist
Frequently Asked Questions

• No limit for time since treatment as long as it is 6 months ago
• Step 2 – pelvic surgery means things like hysterectomy, removal endometriosis, minor debulking, organ prolapse (added to schema)
• If women have two cancer diagnoses, can only enter one (choose most recent)
• Open label confusion: process and dosing
CC004 Cancer Control

PHASE II DOUBLE BLIND DOSE FINDING TRIAL OF BUPROPION VERSUS PLACEBO FOR SEXUAL DESIRE IN WOMEN WITH BREAST OR GYNECOLOGIC CANCER-

LORI SREBINISKI LPN
STACEY LOPEZ LPN
Three ways we get the information to patient

- We review Doctor’s schedule a couple days in advance so we can be present when patient is in the office to present the consent.
- With one office. We also made a letter to introduce the study and it gets mailed two weeks prior to patients appointment. Then when patient is in the office for appointment we can discuss any questions or they also have the option to call us prior to their appointment.
- With one office it helps to be Face to Face, Woman to Woman to go through study.
Things we noticed that were helpful

We added to the name of it just not being about sexual desire but about self awareness since there were questions about self perception after having cancer.

Meeting them in person but then allowing them to read it at home.

Explaining this is not a new drug but a possible new indication for the medication
EFFECTIVE STRATEGIES/BIGGEST CHALLENGES RECRUITING TO NRG-CC004

Shelly McCaskill
Clinical Research Coordinator
Carle Cancer Center
NRG CC004 Flyers
Watch for patients returning for annual visits
Be prepared
Keep conversation casual
Patients do not want to take more medication
Patients do not want to complete questionnaires

BIGGEST CHALLENGES IN RECRUITMENT
WICHITA NCORP

• 11 Medical Oncologists
• 2 Gynecologic Oncologists

- 3 staff members screen for cancer control studies
  • Review daily patient appointment lists for potential patients
  • Discuss the study frequently with physicians
  • Approach dozens of patients
WICHITA NCORP

• Possible barriers to screening
  ● Delicate subject to approach
  ● Physicians reluctant to discuss with patient
  ● Staff may lose motivation after getting rejected

• Persistence is key to success
• Send out reminders to staff and physicians frequently