

97106: A Randomized Study to Determine whether ArginMax Improves the Sexual Function and Quality of Life in *Female Cancer Survivors*

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***Required Sample Size: 144 women have been accrued to this study. An additional 39 minority patients will be accrued. (See section 15.1 last paragraph)**

SCHEMA

- **Stratification:**

Pelvic	vs	Non Pelvic Malignancies
Performance status	vs	0, 1 vs 2
Ovary functional	vs	yes vs no

- **Randomization**

}	Arm 1
	ArginMax 3 caplets twice daily x12wks
}	Arm 2
	Placebo 3 caplets twice daily x 12 wks

OBJECTIVES

Hypothesis: ArginMax will improve sexual function for women who are at least 6 months from active treatment of cancer and are without evidence of cancer.

- **Primary Protocol Objective**

The primary goal is to determine whether ArginMax improves the quality of life and sexual function for women cancer survivors by using the FACT-G and FSFI instruments.

- **Secondary Protocol Objectives**

- 1) To assess differences in quality of life between the two groups.
- 2) To determine differences in toxicity between the two groups.
- 3) To describe the sexual function symptom clusters (if any) in women cancer survivors.
- 4) To assess the effect of race on sexual function and quality of life.

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Eligibility Criteria

- Any female cancer survivor who identifies herself as concerned with her sexual quality of life and answering yes to all three of the screening questions.
 - Are you dissatisfied with your sexual quality of life?
 - Do you have problems with sexual arousal or fulfillment?
 - Are you interested in improving your sex life?
- Must express interest in sexual activity.
- At least 6 months following completion of all cancer therapy. Hormonal therapy and treatment with Herceptin are allowed.
- No evidence of active cancer based on physical exam and / or radiographic images obtained within 3 months of study.
- Absence of any mental, medical or physical disorder known to affect sexual function.
- Absence of participation in another study with an investigational study drug or device during the 30 days prior to start of study drug.
- Lab values must meet the following criteria at study entry: Hgb \geq 10gm/dl, plt \geq 100,000, ANC \geq 1500, creatinine \leq 1.7, T Bili \leq 1.5
- ECOG performance status must be 0-2.
- Must be able to take oral medication
- Must be 18 years old or older

Exclusion Criteria

- History of allergic reactions attributed to compounds of similar chemical or biologic composition to ArginMax.
- Currently taking any blood thinner such as aspirin (one 81mg. aspirin or one baby aspirin daily is allowed), Persantine, Heparin, Lovenox or Coumadin. (Low dose coumadin for catheter patency is allowed.)
- Patients currently taking Ginkgo Biloba are not allowed on this study.
- Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac, arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements and/or ability for sexual function.
- Pregnant women are excluded from this study because ArginMax may be an agent with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with ArginMax, breastfeeding should be discontinued if the mother is treated with ArginMax.
- Because patients with immune deficiency are at increased risk of lethal infections when treated with marrow-suppressive therapy, HIV-positive patients receiving combination anti-retroviral therapy are excluded from the study because of possible pharmacokinetic interactions with ArginMax. Appropriate studies will be undertaken in patients receiving combination anti-retroviral therapy when indicated.
- Any planned surgery during study participation.

Treatment Schedule

All patients will take 3 caplets in the morning and 3 caplets in evening daily by mouth. Pill diaries will be provided. A Sexual Function, Quality of Life, current medications and baseline toxicity information will be assessed prior to study entry, and at 4, 8 and 12 weeks.

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STUDY PARAMETERS

Baseline evaluations and labs are to be conducted within 3 months prior to registration.

	Pre-Study	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12
<u>Study Agent</u>		X	X	X	X	X	X	X	X	X	X	X	X
Informed consent	X												
Demographics	X												
Medical history	X												
Concurrent medication (D)	X				X				X				X
Physical exam	X												
Pulse	X												
Blood Pressure	X												
Height/Weight	X												
Performance status	X												X
Hgb, ANC, platelets (A)	X												
Creatinine, T. Bili (A,B)	X												
B-HCG (C)	X												
TAS (Toxicity Assessment Sheet) (D)	X				X				X				X
FACT – G (E)	X				X				X				X
FSFI (E)	X				X				X				X
Screening Questionnaire	X												
Medication Diary	X				X				X				X
Radiographic Images (F)	X												
Telephone Contact Form (D)					X				X				

** 12 Week assessment should be completed after patient has finished 12 weeks of study medication.
A: Baseline labs should be completed within 3 months prior to registration.
B: Chemistry panel to include creatinine and total bilirubin.
C: Negative serum pregnancy test within 10 days of registration in women of childbearing potential.
D: Toxicity Assessment Sheet (TAS) and concurrent medication sheet needs to be filled out at weeks 4, 8 and 12 if problem noted on telephone contact form.
E: FACT-G & FSFI may be mailed to patient to fill out for weeks 4, 8 and 12.
F: Not required unless using to verify no evidence of disease.

Drug Ordering

ArginMax and matching placebo will be provided free of charge by The Daily Wellness Company. Upon completion of on-line registration Biologics will automatically receive notification of patient enrollment and will contact site personnel for additional information.

Initial labs to be drawn: CBC w/diff, plts, creatinine, total bilirubin

***Study Medication is provided free of charge.**