Wake Forest NCORP Research Base – Protocol 97106

Greven KM, Case LD, Nycum LR, Zekan PJ, Hurd DD, Balcueva EP, Mills GM, Zon R, Flynn PJ, Biggs D, Shaw EG, Lesser G, and Naughton MJ. Effect of ArginMax on sexual functioning and quality of life among female cancer survivors: results of the WFU CCOP Research Base Protocol 97106. The Journal of Community and Supportive Oncology. March 2015; 13(3):87-94. PMID: 26287032 PMCID: PMC4544777 NCT00459134

A total of 186 women cancer survivors experiencing problems with sexual function, satisfaction, or interest were randomly assigned to receive ArginMax (3 capsules twice a day for 12 weeks) or placebo. Sexual function and quality of life were assessed at baseline and at 4, 8, and 12 weeks post randomization. The primary aim of the study was to assess the effect of ArginMax on the Female Sexual Function Index (FSFI) and the FSFI subscales after 12 weeks of therapy. A secondary aim was to assess the effect of ArginMax on quality of life (as quantified by the FACT-G and its subscales). There was no significant effect of ArginMax on sexual function. However, ArginMax did significantly improve several subscales of the FACT-G.

This dataset contains all the data used in the publication cited above.

Baseline demographic and clinical variables are provided for time = 0 (baseline visit).

The primary outcome measures for the study are assessed at each time (0=baseline, 4=4 weeks, 8=8 weeks, and 12=12 weeks).

Summary measures that are calculated across the participant's time on study (e.g., worst toxicities and compliance) are recorded on the time = 99 rows. Note that these are measures determined over the entire study period, not a specific time.

Notes: Missing data are denoted by a blank for each variable.

Corrections: The percent of the maximum ideal dose (denoted at the top of page 6 in the manuscript) should be 66.9 for the placebo group and 66.5 for the ArginMax group.

Data dictionary

Variable	Description	Type	Units	Values
Basic Trial Information				
pid	Participant Identifier	Classification		
group	Randomized arm	Classification		1=Control 2=ArginMax
time	Visit	Classification		0=Baseline 4=4 weeks 8=8 weeks 12=12 weeks 99=Summary measures across the study period
Baseline Demographic and Clinical Information				
age	Participant age	Number	years	
dx2tx	Time from diagnosis to treatment	Number	months	
bmi	Participant Body Mass Index	Number	kg/m^2	
strata	Stratification Factor – Combination of RT type and Primary vs CCOP site	Classification		1=Pelvic Malignancy, Ovarian Function 2=Pelvic Malignancy, no Ovarian Function 5=No Pelvic Malignancy, Ovarian Function 6=No Pelvic Malignancy, no Ovarian Function
raceethnic_grp	Participant race	Classification		H=Hispanic B=Black W=White
ecog	Participant Eastern Cooperative Oncology Group Performance Status	Classification		0=Fully active, able to carry on all pre-disease performance without restriction 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.

Variable	Description	Type	Units	Values
primary	Primary Cancer	Character	Actual cancer	Breast Colorectal Gynecologic Hodgkin's Leukemia Lung Lymphoid Tissue Lymphoma Multiple Myeloma Thyroid
extent	Extent of sexual interest	Classification		1=Extremely uninterested 2=Uninterested 3=Neutral 4=Interested 5=Extremely Interested
overall	Overall sexual satisfaction	Classification		1=Extremely unsatisfied 2=Unsatisfied 3=Neutral 4=Satisfied 5=Extremely satisfied
r_satisfaction	Satisfaction with relationship (excluding intercourse)	Classification		1=No satisfaction 2=Fair 3=Good 4=Very good 5=Excellent
intercourse	Frequency of intercourse	Classification		1=None 2=≤1 time/month 3=>1 time/month but < 3 times/week 4=>3 times/week
climax	Frequency of sexual climax	Classification		1=Never 2=Occasionally 3=Usually 4=Always

Variable	Description	Type	Units	Values
factg_grp	Overall quality of life at baseline as quantified using the FACT questionnaire categorized below and above the median	Classification		1=< median 2=≥ median
physical_grp	FACT physical subscale at baseline categorized below and above the median	Classification		1=< median 2=≥ median
social_grp	FACT social subscale at baseline categorized below and above the median	Classification		1=< median 2=≥ median
emotional_grp	FACT emotional subscale at baseline categorized below and above the median	Classification		1=< median 2=≥ median
functional_grp	FACT functional subscale at baseline categorized below and above the median	Classification		1=< median 2=≥ median
Longitudinal Outcomes				
Sexual Function				
fsfi	Overall sexual function score as quantified by the FSFI questionnaire	Number	Score	2-36; higher better
desire	Desire subscale of the FSFI	Number	Score	1.2-6; higher better
arousal	Arousal subscale of the FSFI	Number	Score	0-6; higher better
lubrication	Lubrication subscale of the FSFI	Number	Score	0-6; higher better
orgasm	Orgasm subscale of the FSFI	Number	Score	0-6; higher better
satisfaction	Satisfaction subscale of the FSFI	Number	Score	0.6-6; higher better
pain	Pain subscale of the FSFI	Number	Score	0-6; higher better
Quality of Life				
fact_g	Overall quality of life (quantified using the FACT questionnaire)	Number	Score	0-108, higher better
physical	FACT physical subscale	Number	Score	0-28, higher better
social	FACT social subscale	Number	Score	0-28, higher better
emotional	FACT emotional subscale	Number	Score	0-24, higher better
functional	FACT functional subscale	Number	Score	0-28, higher better

Variable	Description	Type	Units	Values
Participant measures summarized across the study period				
Adverse Events				
ae_event	Description of adverse event	Character		
ae_grade	Severity grade of the adverse event	Ordinal		0=None 1=Mild 2=Moderate 3=Severe 4=Life-threatening 5=Death
ae_related	Relatedness of the adverse event	Character		Unrelated Unlikely Possible
Toxicities				
nausea*	Worst nausea experienced by the participant over the course of the study.	Ordinal		0=None 1=Mild 2=Moderate 3=Severe 4=Life-threatening 5=Death
vomiting*	Worst vomiting experienced by the participant over the course of the study.	Ordinal		0 – 5
hot_flashes*	Worst hot flashes experienced by the participant over the course of the study.	Ordinal		0 – 5
neuropathy*	Worst neuropathy experienced by the participant over the course of the study.	Ordinal		0 – 5
headaches*	Worst headache experienced by the participant over the course of the study.	Ordinal		0 – 5
Treatment Compliance				

Variable	Description	Type	Units	Values
numdays**	Number of diary days recorded.	Number		
compliance**	Percentage of dose consumed over the recorded diary days.	Number		0-100
percent_ideal**	Percentage of ideal dose over the course of the study.	Number		0-100
Off Study Status				
off_s	Patient's off study status	Classification		2=completed study 4=off due to disease progression 5=off due to toxicity 6=off due to MD decision 7=off due to patient refusal 9=off due to other reasons 21=off due to lost to follow-up 22=off due to surgery

*Values for toxicities are based on the NCI Common Toxicity Criteria (CTC) 3.0

** Numdays is the number of days for which the patient recorded the number of pills they took. Compliance is calculated as the percentage of recorded diary days (numdays) for which the participant took the correct number of pills. For example, the participant was supposed to take 1 pill and actually took 1 pill they got 100% compliance for that day. If the participant was supposed to take 6 pills and took 3 pills, they got 50% compliance for that day. Percent_ideal equals the percentage of total possible pills taken over the entire study period, assuming pills were not taken during unrecorded days and unreturned diaries.