CCCWFU Research Base
Cancer Control Studies

2000 - 2013

Cancer Control Studies

- 21 Cancer Control studies between 2001 – 2013
  - 13 met accrual goals
  - 3 are ongoing and will meet accrual goals
  - 5 did not meet accrual goals (4 due to drug companies withdrawing support, 1 due to poor accrual)
- 3072 Accruals

Characteristic	# (%)
Age	
<20	2 (<1)
20-29	50 (2)
30-39	152 (5)
40-49	576 (19)
50-59	893 (29)
60-69	874 (28)
70-79	455 (15)
80-89	68 (2)
90+	2 (<1)

Characteristic	# (%)
Gender	
Female	2178 (71)
Male	894 (29)
Race/Ethnicity	
White	2154 (70)
Black	549 (18)
Hispanic	277 (9)
ASPI	67 (2)
Other	25 (1)

Characteristic	# (%)
Cancer	
Breast	1657 (54)
Brain	390 (13)
CLL	293 (10)
Prostate	263 (9)
Lung	169 (6)
H & N	159 (5)
Colorectal	40 (1)
GYN	26 (1)
Other	75 (2)

Cancer Control Protocols and Accrual Over Time

Year	# Protocols Open (New)	Accrual
2001	3 (3)	18
2002	5 (2)	69
2003	3 (0)	77
2004	7 (4)	95
2005	6 (0)	174
2006	3 (1)	127
2007	5 (2)	253
2008	6 (2)	467
2009	5 (1)	110
2010	6 (2)	146
2011	5 (1)	213
2012	6 (3)	846
2013	5 (0)	>477

Cancer Control Publications

		Abstracts		Journal Articles	
Status	# Protocols	# Studies	Abstracts	# Studies	# Papers
Terminated Early	5	4	4	1	2
Completed Accrual	13	12	24	7	12
Ongoing	3	0	0	0	0

Completed Studies/Pending Publications

- Abstract
  - Protocol 97211 (Donepezil for “chemobrain” cognitive dysfunction in breast cancer survivors)
- Papers
  - Protocol 60A02 (Juice-Plus in H&N cancer patients))
  - Protocol 97102 (Oxandrin for weight/lean body mass)
  - Protocol 91105 (Donepezil for “beamobrain” cognitive dysfunction in irradiated brain tumor survivors)
  - Protocol 97509 (Armodafinil for fatigue in irradiated primary brain tumor patients)
  - Protocol 97609 (Predictors of radiation-induced acute skin toxicity in breast cancer patients)

Common Assessments across Studies

Outcome	# Protocols	# Patients	Cancers
Cognition	5	451	Brain (389), Breast (62)
CESD	4	455	Breast (312), Brain (68), Lung (64), Others (11)
POMS	3	276	Brain (267), Breast (9)
FAACT	3	193	Lung (89), Colorectal (21), H&N (20), Others (63)
FACIT-F	7	813	Breast (338), Brain (321), Lung (64), Colorectal (21), Others (69)
FACT-B	4	1312	Breast (1312)
FACT-Br	4	389	Brain (389)
FACT-G	16	2511	Breast (1556), Brain (390), Prostate (261), Lung (155), H&N (25), GYN (25), Colorectal (24), Others (75)

Older Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
98199	A Phase III, Double-Blind, Randomized Study of the Effect of Megesterol Acetate on Weight and Health Related Quality of Life in Lung Cancer Patients Receiving Thoracic Radiation Therapy	2000-2002	25	No	Lung	1. Assess the effect of Megace on weight 2. Assess the effect of Megace on QOL	1. Weight 2. FACT-L 3. FAACT	1	0
97300	A Phase III, Double-Blind, Randomized Study of the Effect of Megestrol Acetate on Weight and Health Related Quality of Life in Head and Neck Cancer Patients Receiving Radiation Therapy	2000-2002	13	No	H&N	1. Assess the effect of Megace on weight 2. Assess the effect of Megace on QOL	1. Weight 2. FACT-HN 3. FAACT	1	0
97100	Phase II Study of Donepezil, Gingko Biloba in Irradiated Brain Tumor Patients	2001-2005	69	Yes	Brain	1. Assess the effect of donepezil and ginkgo biloba on neurocognitive function 2. Assess he effect of donepezil and ginkgo biloba on QOL 3. Quantify the extent of radiation-induced white mater disease and temporal lobe atrophy on MRI scans 4. Describe the drug toxicities of donepezil and ginkgo biloba	1. Cognitive battery 2. FACT-Br 3. POMS 4. MMSE 5. MRI Scans	1	5
97600	A Phase III, Double-Blind, Prospective Randomized Clinical Trial of the Effect of Methylphenidate on Quality of Life in Brain Tumor Patients Receiving Radiation Therapy	2001-2005	69	No	Brain	1. Assess the effect of d-MPH on fatigue 2. Assess the effect of d-MPH on QOL 3. Assess the effect of d-MPH on depression 4. Assess the effect of d-MPH on neurocognitive function	1. FACIT-F 2. FACT-Br 3. CES-D 4. Cognitive battery 5. MMSE	2	2

Older Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
97301	STRENGTH (Survival TRaining for ENhancing Total Health) - A Phase II Randomized Study to Assess the Feasability of Dist Medicine Based Exercise + Dietary Approaches to Prevent Body Composition Change Occurring During Adjuvant Chemo for Early Stage Breast Cancer	2002-2004	36	Yes	Breast	1. Estimate relative efficacy of exercise alone or exercise + diet home-based interventions vs a control in preventing increases in percent body fat 2. Estimate relative efficacy of interventions in: a) reducing gains in adipose tissue b) reducing losses in lean body tissue c) reducing gains in weight d) influencing levles of biomarkers e) improving self-efficacy f) reducing depression g) improving QOL 3. Estimate adherence to interventions 4. Assess feasibility of testing home-based exercise and diet interventions using the CCOP infrastructure	1. Percent body fat 2. Adiposity 3. Lean body mass 4. Bone mineral density 5. IGF-1, sex hormone binding globulin, LDL, HDL, Chol 6. FACT-B 7. HADS 8. Cooper Physical Activity Questionnaire 9. Dietary History Questionnaire	0	1
60102	Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients	2004-2008	134	Yes	Head & Neck	1. Assess the effect of JP on p27 and Ki-67 2. Assess the effect of JP on DNA damage and immune function 3. Assess the impact of tobacco, alcohol, and depression on JP effect on biomarkers 4. Assess serum carotenoids and antioxidant levels pre and post treatment	1. p-27 2. Ki-67 3. Clinical	2	0

Older Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
98101	A Phase III Randomized Trial Comparing Sertraline (Zoloft) and Hypericum Perforatum (St. John's Wort) in Cancer Patients with Mild to Moderate Depression	2004-2005	2	No	Multiple	1. Compare the effects of Zoloft and St. Johns Wort on Depressive Symptoms in Cancer Patients with mild to moderate depression	1. HRSD	0	0
97102	A Phase III Randomized Study Comparing the Effects of Oxandrolone (Oxandrin) and Megestrol Acetate on Weight Gain, Body Composition, and Quality of Life in Patients with Solid Tumors and Weight Loss Receiving Chemotherapy	2004-2007	155	Yes	Solid Tumors	1. Compare the effects of Oxandrin and Megace on lean body mass and weight 2. Compare the effects of Oxandrin and Megace on HRQOL	1. BIA 2. FAACT 3. Fatigue 4. PG-SGA	2	0
97202	A Randomized Double-Blind Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients	2004-2009	236	Yes	Breast	1. Assess the effect of CoQ10 on cancer treatment-related fatigue 2. Assess the effect of CoQ10 on QOL 3. Assess the effect of CoQ10 on depression	1. FOMS-F, FACIT-F, VAS 2. FACT-B 3. CES-D 4. MOS 5. CoQ10 6. Alpha tocopherol	3	2
98301	Phase II Study of St. John's Wort for the Treatment of Hot Flushes in Post-Menopausal Women with a History of Breast Cancer	2006-2008	9	No	Breast	1. Assess the effect of St. John's Wort on hot flushes 2. Evaluate the toxicity of St. John's Wort 3. Assess the effect of St. John's Wort on Tamoxifen levels 4. Assess the effect of St' John's Wort on QOL and Mood	1. Hot flush diaries 2. SF-12 3. POMS Short Form 4. Tamoxifen levels 5. Toxicities	1	0

Recent Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
97405	Randomized Study of Soy Protein and Effexor on Vasomotor Symptoms of Men with Prostate Cancer	2007-2010	120	Yes	Prostate	1. Assess the effect of soy and Venlafaxine on the hot flash symptom severity score 2. Assess the effect of soy and Vanlafaxine on QOL 3. Estimate complaince and drop-out	1. Hot flash diaries 2. FACT-P 3. Soy food questionnaire 4. Meds & supplements	1	1
97106	A Randomized Study to Determine Whether ArginMax Improves the Sexual Function and Quality of Life of Female Cancer Survivors	2007-2010	186	Yes	Multiple	1. Assess the effect of ArginMax on sexual function 2. Assess the effect of ArginMax on QOL 3. Assess differences in toxicity 4. Describe sexual function symptom clusters 5. Assess the effect of race on sexual function and QOL	1. FSFI 2. FACT-G 3. Toxicity assessments	1	1
91105	Phase III Double Blind, Placebo Controlled Study of Donepezil in the Irradiated Brain	2008-2011	198	Yes	Brain	1. Assess the effect of donepezil on overall cognitive performance 2. Assess the effect of donepezil on subjective cognitive complaints/symptoms 3. Assess the effect of donepezil on fatigue 4. Assess the effect of donepezil on QOL 5. Assess the effect of donepezil on mood	1. Cognitive battery 2. FACT-Br 3. FACIT-Fatigue 4. POMS 5. Physical Health Questionnaire	8	0

Older Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
98308	A Randomized, Double-Blind, Placebo-Controlled Trial of North American Ginseng Extract to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia	2008-2009	293	Yes	CLL	1. Assess the effect of CVT-E002 on the number of days of acute respiratory illness 2. Assess the safety of CVT-E002 in CLL patients 3. Assess the effect of CVT-E002 on: a) antibiotic use days b) rate of all infections c) duration and severity of ARIs d) major infections e) incidence of herpes zoster f) CLL disease activity 4. Determine the incidence of ARI in an untreated cohort of CLL patients	1. ARI diary 2. Antiboitic use days 3. Influenza/RSV Serology 4. Blood tests 5. Toxicities	0	1

Recent Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
97509	A Phase II, Double-Blinded Feasibility Study of Armodafinil for Brain Radiation-Induced Fatigue	2010-2012	54	Yes	Brain	1. Estimate accrual, adherence, retention, and participation 2. Estimate variability of primary and secondary outcomes 3. Estimate Tx effect on fatigue 4. Estimate rates of toxicities and Aes 5. Estimate Tx effect on: a) sleepiness b) QOL c) cognitive function d) toxicities	1. Feasibility endpoints 2. FACIT-F 3. Epworth Sleep Scale 4. FACT-Br 5. Cognitive Battery 6. Toxicities	1	0
98110	A Randomized Phase II Dose Finding Study of ArginMax with or without Phosphodiesterase-5 Inhibitors for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy	2010-	138	Ongoing	Prostate	1. Determine best dose of ArginMax for treatment of erectile dysfunction 2. Assess toxicity 3. Assess feasibility 4. Assess Tx effect on sexual function and QOL	1. EPIC-26 2. IIEF 3. SEP 4. GEQ 5. FACT-P	0	0
97609	Impact on Genomics and Exposures on Disparities in Breast Cancer Radiosensitivity	2011-2013	1000	Yes	Breast	1. Assess association of nsSNPs and RT-induced skin reactions 2. Assess association of DNA damage and radio sensitivity with RT-induced skin reactions 3. Assess gene-gene and gene-smoking interactions 4. Assess race-ethnic differences in RT-induced skin reactions, DNA damage, and radio sensitivity	1. SNPs 2. ONS Skin Reactions 3. Skindex-16 4. RTOG SOMA 5. Risk Questionnaire 6. B39 QOL 7. FACT-B 8. Blood/Urine	1	0

Recent Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
99211	Feasibility of Delivering a Quitline Based Smoking Cessation Intervention in Lung Cancer Patients Receiving Outpatient Treatment: A Pilot Study	2012-	111	Ongoing	Multiple	1. Assess feasibility 2. Estimate quit rates and Tx effect 3. Assess Tx effect on a) QOL b) stress c) depression	1. Feasibility endpoints 2. Quit Rate 3. FACT-G 4. EORTC 5. CESD	0	0
97211	A Feasibility Study of Donepezil in Female Breast Cancer Survivors with Self-Reported Cognitive Dysfunction Following Chemotherapy	2012-2013	62	Yes	Breast	1. Assess feasibility 2. Estimate variability of outcomes 3. Obtain estimates of Tx effect on prmary and secondary outcomes 4. Correlate fatigue, sleep, and mood with cognitive symptoms 5. Correlate cognitive symptoms and cognitive test performance 6. Document toxicities	1. Feasibility endpoints 2. Cognitive tests 3. FACT-Cog 4. SF-36 5. FACIT Fatigue 6. PROMIS Fatigue 7. Sleep Disurbance 8. Mood States	0	0
99311	Randomized Placebo-Controlled Phase 2 Pilot Study of Memantine (Namenda) for Smoking Cessation among Cancer Survivors	2012-	123	Ongoing	Multiple	1. Assess feasibility 2. Estimate quit rates and Tx effect 3. Assess Tx effect on a) nicotine addiction and withdrawal symptoms b) QOL c) side effects	1. Feasibility endpoints 2. Quit Rate 3. WISDM 4. WSWS 5. SF12	0	0

Recent Cancer Control Protocols

Protocol	Title	Open	SS	Met Target	Population	Aims	Outcomes	Abstracts	Papers
97309	Yoga During Breast Cancer Treatment: Establishing Community-Based Partnerships	2009-2011	40	Yes	Breast	1. Estimate participation, accrual, adherence, and retention to a community based yoga trial 2. Estimate the variability of primary and secondary outcomes 3. Estimate effect of yoga intervention on: a) fatigue b) depressive symptoms c) sleep quality d) QOL	1. Feasibility endpoints 2. FACIT-F 3. MDASI 4. MOS-Sleep 5. CES-D 6. FACT-B	1	1

Opportunities abound!!

- Do you want to lead a paper writing group?
- Do you want to be a member of a writing group?
- Do you have staff or students who are interested in leading or joining a writing group?