Mile Stones

CCCWFU CCOP Research Base

A Semi-annual Newsletter
Winter 2009 Volume 6 Issue 1

Cold Fx Study Reaches Accrual Goal

Kevin High MD, PI

Enrollment in study #98308, **A Phase III Randomized, Double-Blind, Placebo Controlled Trial of North American Ginseng Extract (CVT-E002; COLD-fX®) to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia (CLL)** reached a total of 293 subjects, 13 above the goal of 280, by the end of the open enrollment period December 31, 2008. The study is a randomized, placebo-controlled trial of an extract of North American Ginseng, CVT-E002 (Cold-fX™®, CV Technologies Inc.) to reduce the risk of acute respiratory infections in older adults with untreated CLL. CLL is the most common adult leukemia in developed countries occurring at a rate of 20/100,000 population and accounting for 22-30% of all leukemias; nearly all cases of CLL occur in older adults with a median age of diagnosis of 60-70 years. Infections, particularly respiratory infections, commonly complicate CLL. To date, no complementary/alternative therapy has ever been shown to reduce the risk of infection in CLL patients. Subjects enrolled in this study will be followed throughout the winter respiratory season of 2008-2009 (through April 30, 2009). Sites that enrolled subjects appear in the table.* The ability to enroll nearly 300 subjects in just 2 months is a tribute to the tremendous research teams at these sites. The principal investigators wish to express their extreme gratitude to the recruitment core members at Wake Forest University, and to all the site investigators and coordinators for this monumental achievement!! **See page 2 for individual site accrual information.*

Research Base Ninth Annual Meeting

The Research Base 9th Annual Meeting will be held on September 25-26, 2009. Once again the fall foliage of the Blue Ridge Parkway and downtown Asheville, NC will provide the backdrop of our meeting. The meeting will open with a presentation from Betty Ferrell, PhD, followed by round tables, presentations on recruitment and retention issues, and communication with cancer patients. The reception will be held on the "Top of the Plaza" which is located on the top floor of the Renaissance Hotel and affords spectacular views all around. The meeting will close with reviews of open protocols as well as protocols in development. We plan to open registration in late spring. All information regarding the annual meeting can be found by visiting our website at www.wfubmc.edu/cancer/researchbase/Annual+Meeting. See you in Asheville!

Inside Mile Stones:

- Accrual Goal Reached for Cold Fx
- Save the Date for the 9th Annual Meeting September 25-26, 2009

Wake Forest University Baptist Medical Center
Comprehensive Cancer Center

Mile Stones
CCCWFU CCOP Research Base
Medical Center Boulevard
Winston Salem, NC 27157
336.716.0891
www.wfubmc.edu/cancer/researchbase

CCCWFU CCOP Research Base Open Protocols

91105 Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients
Stephen Rapp, PhD, PI

97106 A Randomized Study to Determine whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors
Kathryn Greven, MD, PI

97202 A Randomized Double-Blind Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients
Glenn Lesser, MD, PI

97405 Phase III Study of Soy, Venlafaxine (EffexorXR™), and Soy + Venlafaxine on Hot Flash Symptoms in Men with Prostate Cancer
Mara Vitolins, RD, PhD, PI

Save the Date!

9th Annual Meeting
September 25-26, 2009
Asheville, North Carolina

98308 Accruals by Site

Wake Forest University Winston Salem, NC	6
Clinical Trials Support Unit	67
Alamance Regional Burlington, NC	5
Hematology Oncology Associates of Central New York East Syracuse, NY	8
Cedar Rapids Oncology Project Cedar Rapids, IA	1
Christian Care Health Services Newark, DE	15
Greenville CCOP Greenville, SC	27
Heartland Research Consortium St. Louis, MO	10
Central Illinois CCOP Decatur, IL	7
Louisiana State University New Orleans, LA	5
Michigan Cancer Research Consortium Ann Arbor, MI	20
Metro Minnesota CCOP St. Louis Park, MN	17
Ozarks Regional CCOP Springfield, MO	13
North Shore University Hospital Manhasset, NY	15
Sioux Community Cancer Consortium Sioux Falls, SD	15
St. Louis – Cape Girardeau CCOP St. Louis, MO	8
St. Vincent CCOP Green Bay, WI	13
Upstate Carolina CCOP Spartanburg, SC	13
SCCC Winston Salem, NC	28
Total	293

The Learning Curve

by Robin Rosdhal RN, OCN

Protocol 91105 (Donepezil / Brain Irradiated Patients) will have a new amendment in the near future allowing patients that have received chemotherapy to be eligible 1 month after completion of therapy vs. 3 months as currently required.

Protocols 97106 (Arginmax / Sexual Function in Female Cancer Survivors) and **97202** (CoQ10 / Fatigue in Female Breast Cancer receiving Chemotherapy) still have a few available slots for new patients.

Protocol 97405 (Soy Protein / Effexor / Hot Flashes in Prostate Cancer) requires a total of 3 patient visits: prescreening to start the 7 day hot flash symptom diary, baseline, and 12/13 week visit. All other patient contact is by telephone. Remember patients may receive concurrent radiation therapy.

Hot Flashes:
Frequently patients have difficulty defining the severity of their hot flashes. Below is a definition of Grades 1-3 hot flashes. There are no Grade 4 or 5 hot flashes.

-- Mild hot flashes (Grade 1) last less than a minute and produce a feeling of warmth with little or no perspiration.
-- Moderate hot flashes (Grade 2) are warmer, produce obvious perspiration, and last 2 to 3 minutes.
-- Severe hot flashes (Grade 3) cause profuse perspiration, generate intense heat, last longer and interfere with ongoing activity (ADL's).

Cognitive Function Training

During the 2008 Annual Meeting at Graylyn International Conference Center in Winston Salem, NC a Cognitive Function Training Workshop was conducted by Dr. Stephen Rapp. The training was for protocol 91105. *(A Phase III Double-Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients)* The purpose of this study is to see if the study drug, donepezil (Aricept ™), will improve the cognitive dysfunction as well as fatigue, mood changes, and poorer quality of life that often occur following radiation therapy for a brain tumor. The protocol requires certification in the administration of the neurocognitive battery for the potential study participants.

Stephen Rapp, PhD

2008 Annual Meeting Training Attendees:

Susan Averson, RN, BSN, OCN, CCRP	Rhonda Kimball
Margaret Crowley, LPN, CCRP	Ashley Parker, BS
Missy Dyar, RN	Claudette Phinney, LPN
June Fletcher-Steede, BS, RT (R)(T), CCRP	Teresa Roberts, RN
Laura Gilliam, RN, BSN	Susan Tuttle, RN, CCRP

On March 25, there will be a one day intensive session aimed at preparing research staff for certification. Training will involve a didactic presentation summarizing the protocol and instructions in how to administer each neurocognitive test, practice administering and scoring them, tips for smooth execution of the protocol and Q&A. For workshop participants who are prepared, we will provide the opportunity to be certified during the workshop. This one day intensive session will be held on the campus of Wake Forest University Baptist Medical Center in Winston-Salem, NC on March 25, 2009. Please contact Lisa Hawkins at lhawkins@wfubmc.edu or (336) 716-0891 to register.

Out and About with June

We are currently entering the audit phase of our time table. Be on the lookout for notification that your site is due for an audit. If you have any questions regarding these audits, please contact me at jsteede@wfubmc.edu or 336- 716-6733.

June Fletcher-Steede