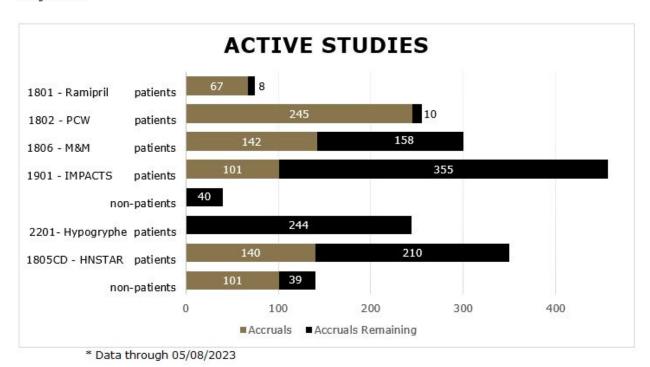


Quarterly Newsletter May 2023



Study Highlight

WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy



Primary Objective

To compare the proportion of participants experiencing Grade 2 or higher Adverse Radiation Effects (ARE) within 9 months following randomization to single fraction stereotactic radiosurgery (SSRS) vs fractionated stereotactic radiosurgery (FSRS) in patients with brain metastases >=2 cm in diameter or >=4cc in volume treated with concurrent immune checkpoint inhibitor (ICI) therapy.

Hypothesis

Reduction in Grade 2 or higher ARE from 22.5% with SSRS to 7.1% with FSRS (15.4% reduction).

Study Population

Melanoma, renal cell, non-small cell lung or breast cancer patients with brain metastases (<=15 metastases) currently receiving or planning to receive PD-1/PD-L1 targeted immune checkpoint inhibitor therapy within 30 days of SSRS/FSRS.

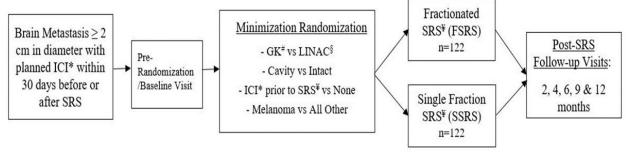
Sample Size Total=244 (122 FSRS arm; 122 SSRS arm)

Future Amendments

Planning to extend the window for starting treatment after the planning MRI to 14 days based on feedback from sites.

If you have any items that you would like to be considered for a future amendment that would clarity the protocol or help with recruitment let us know.

Study Schema



The protocol and all documents are available on the CTSU website. The introductory webinar is available on our website, Wake NCORP Website: https://wakencorp.phs.wakehealth.edu/ [wakehealth.us19.list-manage.com]

If you would like to be involved in this study, please contact us at NCORP@wakehealth.edu for more information.

Top 3 Accruing CC Affiliates*

Rank	Affiliates	
1	IL042 - John H Stroger Jr Hospital of Cook County (Stroger MU)	6
2	AL002 - University of Alabama at Birmingham Cancer Center	5
3	SC024 - Spartanburg Medical Center (Upstate)	3

^{*} Data from 01/01/2023 - 03/31/2023

Top 3 Accruing CCDR Affiliates*

Rank	Affiliates	Accruals
1	VA010 - VA/Massey Cancer Center (VCU MU)	35
2	OK010 - Mercy Hospital Oklahoma City (Ozarks)	13
3	IA024 - Oncology Associates at Mercy Medical Ctr (IWORC)	10

^{*} Data from 01/01/2023 - 03/31/2023

Site Highlight: Montefiore Minority Underserved NCORP

Montefiore Einstein Cancer Center

Montefiore Minority/Underserved NCORP is proud to serve one of the most ethnically diverse populations in the nation in The Bronx, New York. With over 1.4 million Bronx residents, we have an opportunity to engage patients who belong to groups underrepresented in research as more than 80% of the population of the Bronx belong to one of these key groups. Our NCORP is led by **Dr. Balazs Halmos MD (Contact PI, below left), Dr. Benjamin Gartrell MD (PI of Therapeutic Trials, below center), and Dr. Bruce Rapkin PhD (CCDR Lead, below right).** Our NCORP includes 5 sites and 1 affiliate, with 15 investigators and 14 research staff. Across Montefiore Einstein Cancer Center, we have over 320 clinical trials in progress, which give patients access to some of today's most advanced treatments with more than 80% of our patients participating in our clinical trials belonging to underrepresented groups.

Montefiore Einstein Cancer Center treats over 4,000 patients annually with a broad range of cancer diagnoses and provides the vibrant and diverse communities we serve with the resources needed to make informed decisions about their health, from cancer screenings and advanced cancer treatment options to supportive services, including dedicated cancer navigators offering step-by-step guidance. We provide health education through a variety of community engagement programs and events, and proudly serve as an anchor in our vibrant and diverse urban communities. We also have an active program of research to develop and test multilevel strategies to encourage and support participation on clinical trials.

We have expertise in all cancer types, including those that are rare or call for complex management. Our clinical experts work in disease-focused multidisciplinary team models and are supported by dedicated psychosocial support staff. Close engagement between clinicians and translational scientists yields an academically rigorous and patient-centered environment to optimize patient outcomes.







Do you have site or staff that should be recognized? Please submit recommendations to MCORP@wakehealth.edu with "Quarterly Newsletter Site/Staff Highlight" in the subject line.

Top Accruing Investigators by Study

(from 01/01/2023 - 03/31/2023)

WF-1801

- Zachary Vaslow, MD (2) NC004, SCOR
- 2. Michael Chan, MD (1) NC002
- 2. Vijay Damarla, MD, MPH (1) IL352, Heartland

WF-1802

- Deimante M. Tamkus, MD (4) IL042, Stroger MU
- Michael Humeniuk, MD (2) SC024, UPSTATE
- Joseph Pennington, MD (2) VA217, SCOR
- 2. Payal Dilip Soni, MD (2) NJ048, Atlantic

WF-1804CD

- Mary Helen Hackney, MD (35) VA010, VCU MU
- 2. Sonia John Varghese, MD (10) OK010, Ozarks

WF-1805CD

- Rafi Kabarriti, MD (3) NY045 & NY313, Montefiore MU
- 1. Matthew Pierce, MD (3) DC007, Capital MU
- 1. Brandon Wilson, CNP (3) OH122, Columbus
- 2. Amarinthia (Amy) Curtis, MD (2) SC024, Upstate
- Evan M. Graboyes, MD, MPH (2) SC008, MUSC MU

WF-1806

- 1. Grant Williams, MD (5) AL002, UAB
- 2. Kathleen Beekman, MD (2), MI017, MCRC

WF-1901

- Lillian Klancar, MD (2) CO125, Kaiser
- Meghan Liel, MD (2) CO112, Kaiser
- 2. 13 other investigators accrued 1 each

Top CC Accruing Investigators

(from 01/01/2023 - 03/31/2022)



Grant Williams, MD AL002, UAB (5)



Deimante M. Tamkus, MD IL042, Stroger MU (4)

Top CCDR Accruing Investigators

(from 01/01/2023 - 03/31/2022)



Mary Helen Hackney, MD VA010, VCU MU (35)



Sonia Varghese, MD OK010, Ozarks (10)

Meet Wake Forest NCORP Research Base Staff: Heather Lawson



Heather Lawson has been a Project Manager with the Wake Forest NCORP RB since February of 2020 working in the areas of site coordination, auditing and data management. Prior to joining the Research Base team, Heather worked for the WFU Baptist Medical Center (Now Atrium Health Wake Forest Baptist) as part of the Department of Pathology where she served as a laboratory manager specializing in Hematology. Heather holds a B.S. in Clinical Laboratory Science and an MHA from UNC Chapel Hill and found a love for research in the years spent in the WF School of Medicine Special Hematology and Protocol Support Lab. Heather has recently transitioned to a Program Manager position to oversee and optimize site coordination services and recruitment endeavors and is excited to learn more ways to support our constituent sites. Heather is married with two adult children, ages 23 and 21. In her spare time, Heather enjoys cooking, playing with her dogs and spending time with family and friends.

WF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience

This study will be closing to accrual on August 1, 2023

Please make one last effort to identify and enroll eligible participants prior to this date. In order to capture as much follow up data possible, please be sure to make all contact attempts for participants still on study to complete the 3 and 6 month questionnaires.

Thank you for all of your hard work on this study!

We have the following slots available: Higher Income, AA- 6 slots available Lower Income, White – 33 slots available

To determine the remaining slots left for any stratum in real time, visit CTSU-OPEN>Slot Reservation>Report.

New Publications & Presentations

Publications

- Danhauer SC, Dressler EV, Brown WM, et al. Reducing Anxiety and Dyspnea via Device-Guided Breathing (RELAX): A Multi-Site Feasibility Study in Post-Treatment Lung Cancer Survivors at Community Cancer Clinics (WF-01213). Integrative Cancer Therapies. 2023. (Published April 8)
- Foley KL, Dressler EV, Weaver KE, et al. The OaSiS Trial (WF-20817CD): Multi-Center Randomized Effectiveness Implementation Trial to Increase Smoking Cessation for Individuals Undergoing Lung Screening. CHEST. 2023. (Published March 15)
- Suddala S, O'Connell N, D'Agostino Jr R, et al. Reduced Thoracic Aortic Distensibility Upon Breast Cancer Diagnosis (WF-97415 and WF-98213). Cardio Oncology. 2023. (Published March 7)
- Bellissimo MP, Reding KW, O'Connell NS, et al. Intermuscular Fat Changes Are Related to Reduced Left Ventricular Ejection Fraction During Cancer Therapy (PREVENT-WF-98213). Cardio Oncology. 2023. (Published February 20)

Presen	tations	& Ahs	tracte

Study	Title	Authors	Conference	Acceptance & Format	Date
WF-1804CD	Effectiveness of a cardiovascular health EHR application for cancer survivors in community oncology practice: Results from WF-1804CD	Weaver KE, Dressler EV, Klepin HD, Wells BJ, Smith S, Hundley WG, Lesser GJ, Nightingale CL, Throckmorton A, Hernandez M, Hanna JM, Lackey I, Heard K, Foraker R.	American Society of Clinical Oncology, Chicago, IL	Oral presentation in the Symptoms and Survivorship session	June 2-6, 2023
WF-1804CD	Cost and time estimates for integrating a cardiovascular health application for cancer survivors in the electronic health record: Case studies from the NCORP network.	Foraker R, Durken M, Lackeya, et al.	American Society of Clinical Oncology, Chicago, IL	Online publication	June 2-6, 2023
LANDSCAPE	Sexual Orientation and Gender Identity Data Collection among NCI Community Oncology Research Program (NCORP) Sites: A 5-year Landscape Update.	Cathcart-Rake E, Jatoi A, Dressler EV, et al.	American Society of Clinical Oncology, Chicago, IL	Online publication	June 2-6, 2023
LANDSCAPE	The 2022 NCI Community Oncology Research Program (NCORP) Landscape Committee Assessment: Methods and Participating Practice Group Characteristics.	Nightingale CL, Dressler EV, McDonald AM, Neuman HB, Parsons SK, Foust M, Cooley ME, Obeng-Gyasi S, Braun-Inglis C, Loh KP, Kyono WT, Drescher CW, Ramsey SD, Wood EG, Kittel CA, Lesser GJ, Weaver KE.	American Society of Clinical Oncology, Chicago, IL	Online publication	June 2-6, 2023
ANDSCAPE	Availability of palliative specialty care for adults in community oncology: Results from the 2022 NCORP Landscape Survey.	Statler T, Kittel C, Dressler EV, et al.,	American Society of Clinical Oncology, Chicago, IL	Online publication	June 2-6, 2023
WF-97116	Phase 3 randomized placebo-controlled trial of donepezil for cancer-related cognitive impairment among breast cancer survivors: Results on patient-reported cognitive function from the Wake Forest NCI Community Oncology Research Program	Ernster AE, Dressler EV, Brown WM, Lesser GJ, Balcueva E, Fusselman W, Gudena V, Wagner LI, Klepin H, Shaw EG, Rapp SR.	American Society of Clinical Oncology, Chicago, IL	Poster presentation in the Symptoms and Survivorship Session	June 2-6, 2023
WF-97116	Phase 3 randomized placebo-controlled trial of donepezil for late cancer-related cognitive impairment in breast cancer survivors exposed to chemotherapy from the Wake Forest NCI Community Oncology Research Program (NCORP) Research Base REMEMBER trial (WF97116).	Rapp SR, Dressler EV, Brown WM, Wade J, Le- Lindqwister N, King D, Rowland K, Weaver KE, Klepin H, Shaw EG, Lesser GJ.	American Society of Clinical Oncology, Chicago, IL	Oral presentation in the Symptoms and Survivorship session	June 2-6, 2023
WF-97415	The impact of treatment, physical activity, and other factors on upper extremity function at 3-months post initiation of chemotherapy for breast cancer: Results from WF 97415.	Page LL, Brubaker PH, Klepin HD, Avis AE, Levine BJ, Hundley WG, Weaver KE, Lesser GJ, Mihalko SL.	Society of Behavioral Medicine, Phoenix, AZ	Poster Presentation	April 26-29, 2023
WF-97415	Declines in Social Support during Breast Cancer Treatment and their Association with Exercise Capacity Reductions in Breast Cancer Survivors (WF-97415).	Nguyen J, Reding KW, D'Agostino R, Ladd A, Szewczyk W, Lucas AR, Mihalko S, Weaver KE, Lesser GJ, Hundley WG.	Western Institute of Nursing Conference, Tucson, AZ	Poster Presentation	April 19-22, 2023
WF-97609	Radiotherapy-Induced Early Adverse Skin Reactions: Comparative Analysis of Clinician- and Patient-Reported Outcomes in a Multi- Racial/Ethnic Breast Cancer Population (WF- 97609).	Urbanic JJ, Shaw EG, Takita C, Wright JL, Ip EH, Lu L, Baez Diaz L, Brown DR, Strasser J, Baglan K, Palmer M, Thakrar A, Curtis AE, Lesser GJ, Hu JJ.	American Association for Cancer Research, Orlando, FL	Poster Presentation Population Sciences: Cancer Disparities	April 14-19, 2023
WF-1803CD	Oncology Provider Perspectives on Supporting Cancer Caregivers: A National Cancer Institute Clinical Oncology Research Program (NCORP) Study (WF-1803CD Caregivers)	Sterba KR, Weaver KE, Snavely A, Dressler EV, McLouth L, Kent E, Adonzio C, Wojtowicz M, Cannady R, Nightingale C	American Society of Preventive Oncology, San Diego, CA	Poster Presentation	March 12-14, 2023
MPACTS WF- 1901	Developing a Culturally Appropriate Non-Opioid Pain Coping Skills Training Intervention for Spanish-Speaking Patients with Cancer Pain Using a Community Engaged Approach	Trejo G, Pardy M, Henighan T, Ramos K, Irby MB, Penzien DP, Dressler E, Keefe F, Lesser GJ, Rini C, Snavely A, Vitolins MZ, Weaver KE,	HEAL Investigators Conference	Poster Presentation	February 21- 22, 2023
MPACTS WF- 1901	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS WF-1901)	Hennighan TF, Irby MB, Pardy MR, Lawson H, Turner J, Young CB, Craver K, Booth S, Brown M, Stanfield B, Dressler EV, Snavely AC, Danhauer S, Ang D, Vitolins MZ, Rini C, Keefe FJ, Weaver KE, Lesser GJ, Penzien DB	HEAL Investigators Conference	Poster Presentation	February 21- 22, 2023

Health Equity Core Updates

The HEC Co-leaders were honored to be invited to the Southeast Clinical Oncology Research Consortium (SCOR) NCORP conference to help train patient advocates. Dr. Winkfield was also a featured speaker on diversity in clinical trials. Diamond Suber, our ARM patient advocate, also told her story to help remind us why we do what we do- provide innovative treatment options to patients with cancer.



Dr. Karen Winkfield and Diamond Suber (above)



Dr. Karen Winkfield and Susan Tuttle from SCOR (above)

The Wake Forest NCORP Research Base Health Equity Core focuses on recruitment & retention of minority/underserved populations. This group meets quarterly to share best practices, influence study design, discuss community engagement strategies and share resources and tools. If you are interested in joining this group, please contact us

at NCORP@wakehealth.edu

Wake Forest NCORP Research Base Annual Meeting Update



The 2023 Wake Forest NCORP Annual Meeting dates will be October 16-17, 2023. This will be a Monday/Tuesday meeting.

The location will be The Renaissance in Asheville, NC.

Meeting registration and hotel information will be available soon.

WF NCORP RB Quarterly Calls

The April 12, 2023 quarterly call Webex has been added to the Wake NCORP website. If you missed it - Use this link to access the recording: https://vimeo.com/817361342

The next quarterly call is Wednesday, July 26, 2023 at 3 pm EST.

Recipe: Pineapple Green Smoothie



Ingredients

- ½ cup unsweetened almond milk
- ⅓ cup nonfat plain Greek yogurt
- 1 cup baby spinach
- 1 cup frozen banana slices (about 1 medium banana)
- ½ cup frozen pineapple chunks
- 1 tablespoon chia seeds
- 1-2 teaspoons pure maple syrup or honey (optional)

Directions

Add almond milk and yogurt to a blender, then add spinach, banana, pineapple, chia seeds and sweetener (if using); blend until smooth.

^{*}Recipe from EatingWell.com





SketchQuotes by Nelle Rhicard at www.reframeideas.com [reframeideas.com]



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