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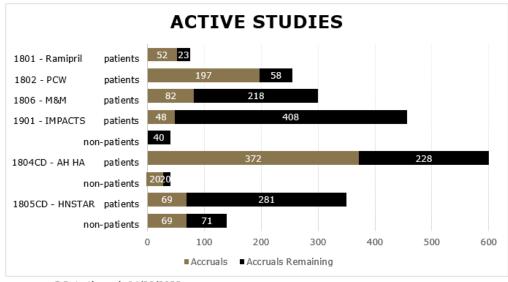
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COMMUNITY CONNECTION

Quarterly Newsletter April 2022

Study Accruals



^{*} Data through 04/28/2022

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WF-1801 Ramipril

A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy

For patients scheduled to receive partial brain radiotherapy and temozolomide (or chemotherapy) for newly diagnosed Glioblastoma (GBM). This is a single arm pilot study of Ramipril 2.5-5mg titrated to prevent cognitive decline in patients receiving partial brain RT.

Brief Eligibility Criteria: ≥ 18 years old; pathologically proven GBM; planned to receive brain RT and concurrent temozolomide chemotherapy; ECOG 0, 1 or 2; Baseline HVLT-R Delayed Recall score must be submitted.

Study Sample: N=75

Study Duration: Approximately 6 months

This study was recently amended to assist with recruitment, clarify the protocol, and make it easier for sites to participate.

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

SCHEMA

Screen, recruit, consent and register patients scheduled to receive partial brain radiotherapy and temozolomide (or chemotherapy) for newly diagnosed Glioblastoma (GBM)

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Baseline: MRI Brain

History and physical, Blood pressure, current medications

Neurocognitive Test Battery

Participant Reported Outcome Questionnaires (PRO)

Blood draw for chemistry, pregnancy test (if applicable) and Apolipoprotein epsilon genotype (ApoE)

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Ramipril capsules daily x (6 weeks of RT course + 4 months)

(Week 1of RT: one 1.25 mg capsule orally once a day)

(Week 2 of RT: two 1.25 mg capsules (2.5 mg total orally once a day) (Week 3 of RT: four 1.25 mg capsules (5 mg total orally once a day)

Continue on maximally tolerated dose (2.5-5 mg orally once a day) for 4 months post RT

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Interventions

Weeks 1-3: Administration/titration of study drug, weekly toxicity assessment by Study Team, obtain medication

diaries for compliance and verify dosage, blood pressure and blood draw

Weeks 4-5: Administration of maximally tolerated study drug, weekly toxicity assessment by Study Team, obtain

medication diaries for compliance and verify dosage, blood pressure and blood draw.

Week 6 - RT completion: Administration of maximally tolerated study drug, Study Team toxicity assessment, obtain medication

diaries for compliance and verify dosage, blood pressure. Repeat neurocognitive battery and PRO

questionnaires.

1 Month Post RT (Wk10): Administration of maximally tolerated study drug, Study Team toxicity assessment, obtain medication

diaries for compliance and verify dosage, blood pressure, MRI brain. Repeat neurocognitive battery and

PRO questionnaires

2, 3 Month post RT (Wk 14, 18): Administration of maximally tolerated study drug, Phone interview for toxicity assessment, verify study

medication dosage and compliance (request medication diaries be returned in-person or via mail)

4 Month post RT (Wk 22): Study Team toxicity assessment, obtain medication diaries for compliance, verify dosage and collect any

remaining study medication, blood pressure, MRI brain. Repeat neurocognitive battery and PRO

questionnaires

5 Month post RT (Wk 26): Phone interview for toxicity assessment

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Rank	Affiliates	Accruals		
	SC024 - Spartanburg Medical Center (UPSTATE)			
1	IL042 - John H Stroger Jr Hospital of Cook County (STROGER MU)	8		
2	NC002 - Wake Forest University Health Sciences	7		
3	IL168 - Carle Cancer Center (CARLE)	3		
4	SC101 - Gibbs Cancer Center - Pelham (UPSTATE)			
	SC060 - Prisma Health Cancer Institute - Faris (PRISMA HEALTH)			
	MN001 - Regions Hospital (METROMIN)	2		
	HI012 - Kapiolani Medical Ctr for Women & Children (HAWAII MU)			
	* Data from 1/1/2022 - 3/31/2022			

*	Data	from	1/1/2022	- 3/31/2022

Rank	Affiliates	Accruals		
1	AR012 - Mercy Hospital Fort Smith (OZARKS)	39		
2	WI212 - ThedaCare Regional Cancer Center (WINCORP)	27		
3	MO043 - Mercy Hospital Springfield (OZARKS)	24		
4	TN143 - Baptist Memorial Hospital for Women (BAPTIST MU)	9		
	SC008 - Medical University of South Carolina (MUSC MU)	3		

^{*} Data from 1/1/2022 - 3/31/2022

Site Highlight



Mission: Upstate Carolina NCORP provides NCI clinical trials to improve the quality of life and survival in cancer patients.



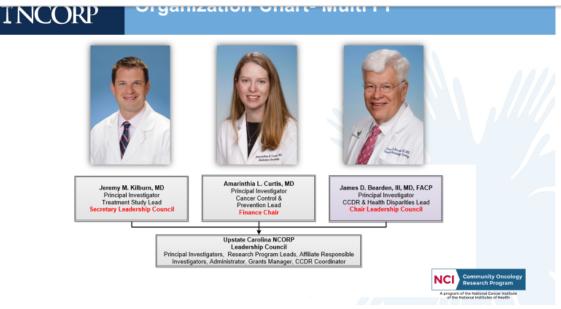
Table Rock, Upstate South Carolina

Upstate Carolina NCORP

The Upstate Carolina Consortium NCI Community Oncology Research Program (NCORP) integrates 3 affiliates (AnMed Health, Bon Secours St. Francis, and Spartanburg Regional Healthcare System – Gibbs Cancer Center) who together have a well-established history of NCI research participation: Community Clinical Oncology Program (CCOP) 1983 to 2014 and NCORP 2014 to present.

Upstate Carolina Consortium NCORP (UC-NCORP) has 48 experienced and engaged community investigators led by 3 Principal Investigators, 1 medical oncologist and 2 radiation oncologists, with early, mid to senior levels of experience. The 3 affiliate research programs are located within community hospitals serving the upstate of South Carolina and adjacent areas of North Carolina and Georgia.

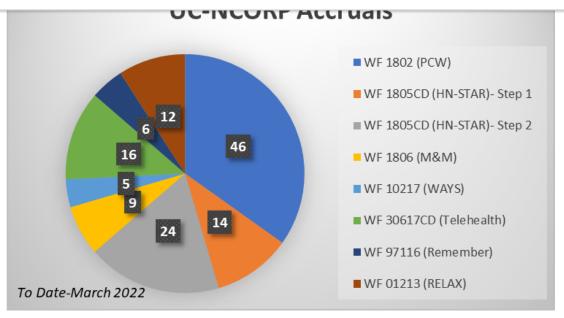
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Over the years, UC-NCORP has built a solid relationship with the Wake Forest Research Base. The UC-NCORP staff appreciates Wake Forest Investigators, Project Managers, and staff; their responsiveness and receptiveness are unparalleled. UC-NCORP has successfully participated in WF-1806 (M&M), WF-10217 (WAYS), WF-30917CD (Telehealth) and WF-97116 (REMEMBER). The spirit of collaboration has allowed UC-NCORP to lead the nation in WF-1802 (PCW) and WF-1805CD (HN-STAR) accruals!

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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.

Research Staff Spotlight

Abdelmohsen Alqalam, MBA, Senior Research Coordinator, works on the Cancer Control and CCDR Team in the Clinical Research department of Gibbs Cancer Center. Mohsen, as friends and colleagues call him, charms all with his positive attitude and exemplary work

Ask about the motivation behind his passion for Cancer Care Delivery Research and the WF-1805CD HN STAR trial, and Mohsen will tell you a story:

A 23-year-old happy newlywed went to his primary care physician to have a mouth sore checked. Thinking it was nothing, Shadi was

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and multiple surgeries. Two thirds of his tongue was lost! Unfortunately, Shadi was not offered a single speech therapy session to help with swallowing and speech but that did not stop him, so he fought to teach himself to speak again. He struggled with eating and lost significant weight but was never offered a dietitian or nutritional consult. Again, Shadi fought to overcome this obstacle as well. The way he looked did not stop him, he continued to work in his own boutique and his customers continued to love him.

The lack of a solid support system and survivorship plan finally led to disaster. During his last treatments, Shadi was malnourished; he wasn't offered a feeding tube and became weak and unable to tolerate his high-dose pain medications. Unfortunately, due to the lack of supportive care, he suffered respiratory arrest and multiple massive myocardial infracts at once. In the end, Shadi was transferred to the ICU. As the hospital was under Covid precautions, Shadi passed away alone.

Mohsen seeks to enroll WF-1805CD patients so that Survivorship Care will be improved and will be offered to all head and neck patients as standard of care. He urges others to never underestimate the power of what we do when it comes to survival planning for our cancer patients. Mohsen knows that Survival Care it is at the same level of importance as the chemotherapy and radiation used to treat the cancer. Giving cancer survivors more years to live but without quality of life is torture.

As you may have surmised, Shadi is Mohsen's brother. Asked about Shadi, Mohsen offers this, "Superman, Batman and Spiderman are fake heroes, but Shadi is a real one, and he is my hero of all times."

Below are pictures of Mohsen and his hero, Shadi Alqalam

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WF-1801

- 1. Emory McTyre, MD (1) SC060, PRISMA HEALTH
- 2. Roy Ervin Strowd, MD (1) NC002

WF-1802

- 1. Deimante M. Tamkus, MD (8) ILO42, STROGER MU
- 2. Ashok K. Hemal, MD (6) NC002

WF-1804CD

- 1. Jenny Marie Hanna, NP (25) AR012, OZARKS
- 2. Dana Reeves, ARNP (14) AR012, OZARKS

WF-1805CD

- 1. Evan Graboyes, MD (9) SC008, MUSC MU
- 2. 9 other investigators have 3 accruals

WF-1806

1. 9 investigators have 1 accrual

WF-1901

- 1. Christa Braun-Inglis, NP (2) HI012, HAWAII MU
- 2. 10 other investigators have 1 accrual

Top CC Accruing Investigators

(from 1/1/2022 - 3/31/2022)



Deimante M. Tamkus, MD IL042, STROGER MU (8)



Ashok K. Hemal, MD NC002 (6)



Drew Monitto, MD SC024, UPSTATE (4)

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Jenny Marie Hanna, NP AR012, OZARKS (25)



Dana Reeves, APRN AR012, OZARKS (14)

Meet Wake Forest NCORP Research Base Staff: Dell Campbell

Dell is a Protocol Specialist and has worked with Data Management in the NCORP Research Base for 10 years. She attended East Carolina University in Greenville, NC. She currently monitors data quality for the AH-HA and HN-STAR studies. She also maintains all electronic files for the submitted data and correspondence for these studies. Many of you have worked with her on the PREVENT study and have gotten to know her via phone calls, emails and at our Annual Meeting. She likes fabrics and clothing by April Cornell. She also likes music by the Eagles, shopping, and being with friends and coworkers. The picture with Rhonda and Dell was taken in Greenville, SC at one of our annual meetings where they took a carriage ride through town. She loves to travel and one day would like to make a return visit to Scotland. She is upbeat and fun to be around as evidenced by her Halloween costume one year, when she and her neighbor dressed up as Chip and "Dell". Dell has one daughter, two grandchildren and a very "large" cat named Sam who keeps Dell in line.

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Study	Al:	ostract Title	Authors	Conference	Format	D	ates
IMPACTS	WF- Pa	ternet-delivered Management of in Among Cancer Treatment Irvivors (IMPACTS WF-1901)	Irby, MB, Penzien, DB, Dressler, EV, Lesser, GJ, Rini, CM, Keefe, FJ, Weaver, KE, Snavely, AC, Rapp, SR, Vitolins, MZ, Ang, DC, Craver, K, Young, CB, Rodriguez-Pardy, M	ASCO	In-Person Poste	er	ine 3-7)22
Landscape	e for	lliative specialty care availability adults in community oncology actices	Klepin, H, Statler, TM, Lesser, GJ, Weaver, KE	ASCO	Online publicationly		ine 3-7 022
ACUPUNC WF97115	Or (N TURE Sh Ac Ra in	Phase III, NCI Community ancology Research Program CORP) based, Randomized, sam-controlled Trial of upuncture for Treatment of diation-Induced Xerostomia (RIX) Patients with Head and Neck sincer	Cohen, L. Danhauer, S, Rosenthal, DI, Chamber, M, Ochoa, J, Cusimano, A, Yang, P, Brown, WM, Dressler, EV, Garcia, K, Crutcher, R, Gordon, O, Kim, JK, Clarins, D, Russin, M, Lukenbill, J, Porosnicu, M, Yost, K, Weaver, KE, Lesser, GJ	ASCO	Oral presentation as part of the survivorship panel for June 6		ine 3-7 022
UPBEAT W	VF97415 an	npact of cardiometabolic health d abdominal adipose tissue on ysical function in women with east cancer (WF-97415)	Heiston, EM, Mabudian, L, O'Connell, NS, D'Agostino, RB, Brubaker, P, Mihalko, SL, Reding, K, Bellissimo, MP, Ladd, AC, Lucas, AR, Jordan, JH, Ky, B, Calhoun, T, Hackney, MH, Weaver, KE, Lesser, GJ, Hundley, G	ASCO	Online publicationly		ine 3-7 022
UPBEAT W	VF97415 ch	e impact of anthracycline-based emotherapy on fatigue: Results om WF-97415	Avis, NE, Levine, B, Mihalko, SL, Klepin, HD, Brubaker, P, Calhoun, T, Dent, S, Ky, B, Ladd, A, Ntim, WE, Wagner, LI, Weaver, KE, Hundley, WG	ASCO	Published onlin	e only	ine 3-7 022
UPBEAT W	VF97416 co	EF decline in relation to body mposition among women treated breast cancer: WF-97415	Reding, KW, O'Connell, NS, Cheng, RK, Nguyen, J, Ladd, A, Jordan, J, Ky, B, Vasbinder, A, Calhoun, T, Hackney, MH, Bellissimo, M, Langford, D, D'Agostino, R, Lesser, GJ, Hundley, WG	ASCO	Accepted		ine 3-7 022
M&M WF1	.806 To:	vopenia and Mechanisms of xicity in Older Adults with olorectal Cancer (CRC): The M&M udy (WF-1806)	Williams, GR, Klepin, H, Sanoff, H, Muss, H, Al- Obaidi, M, Harmon, C, Richman, J, Dressler, E, Bhatia, S, O'Rourke, MA, Weaver, KE, & Lesser, GJ	ASCO	Poster		ine 3-7 022
Caregivers	s 1803 Pa	tient and informal caregiver	Weaver KE, Sterba K, Snavely A, Dressler E,	Multinational	Oral presentation	on Ju	ine 23

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		Moore T, Kehn H, & Nightingale C	Cancer			
Caregivers 1803 CD	Patient and caregiver supportive care availability and funding sources among National Cancer Institute Community Oncology Research Program Practices	Nightingale, C, Weaver, K, Snavely, A, Dressler, E, Danhauer, S, McLouth, L, Kent, E, Adonzio, C, Wojtowicz, M, Cannady, R, Kehn, H, Hopkins, J, Kuzma, C, Moore, T, and Sterba, K	Multinational Association of Supportive Care in Cancer	E-Poster	June -25	e 23 2022
WF97415 UPBEAT	The Association Between Visceral Fat and Left Ventricular Performance in Stage I-IV Breast, Lymphoma, and Sarcoma Cancer Patients that Receive Cardiotoxic Chemotherapy	Leila Mabudian, Nathaniel S. O'Connell, Ralph B. D'Agostino, Emily Heiston, Julia A. Fleshman, Daniel Miller, Kerryn Reding, Kathryn E. Weaver, Amy Ladd, William Ntim, Heidi Klepin, Emily Dressler, Tonya Calhoun, Jennifer Jordan, Mary Helen Hackney, Glenn Lesser, William G. Hundley	American College of Cardiology Conference	Virtual moderal poster presenta		l 2-4 2
WF98213 PREVENT	Accuracy of rapid cardiovascular magnetic resonance assessment of left ventricular function	Leila Mabudian, Ralph D'Agostino, Jennifer Jordan, Madalyn B. Martin, Julia Fleshman, Teresa Crotts, Amy Ladd, Glenn Lesser, Mary Helen Hackney, William G. Hundley	American College of Cardiology Conference	Virtual moderal		l 2-4 2
WF98213 PREVENT & WF97415 UPBEAT	Reduced Aortic Distensibility in Breast Cancer Patients Prior to Treatment	Suhas Suddala, Dr. Amy Ladd, Dr.Ralph D'Agostino, Daniel Miller, Nate O'Connell, Dr. Alex Lucas, Dr. Jennifer Jordan, Dr. Glenn J. Lesser, Dr. Kathryn E. Weaver, Teresa Crotts, Tonya Calhoun, Dr. Giselle Melendez, Dr. Alexandra Thomas, Dr. Mary Helen Hackney, Dr. Gregory Hundley	American College of Cardiology Conference	In-person poste	er Apri 202	l 2-4 2

Health Equity Core Updates

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 <a href="https://www.ncore

Accomplishments: For our current WF NCORP active studies our minority accrual is at 20%!

Annual Meeting: Please plan to attend the WF NCORP RB Annual Meeting, October 10 -12, 2022 as the Health Equity Core will sponsor the Keynote Speaker followed by a panel discussion which will focus on minority/underserved populations.

National Minority Health Month!

and improve the health of racial and ethnic minority and American Indian/Alaska Native communities. For more information about upcoming events, click on the link below.

https://www.minorityhealth.hhs.gov/nmhm/?utm campaign=health equity link&utm medium=email&utm source=govdelivery





Descarga

Upcoming Meetings

We invite all NCORP CCDR Leads and interested site investigators and staff to save the date for a half day CCDR workshop led by investigators from the iDAPT: Implementation and Informatics P50 Center. The focus will be on building capacity to participate in implementation science CCDR studies, including information on assessing your practice readiness and engaging stakeholders. The inperson workshop will be immediately following the Wake Forest NCORP Research Base Annual Meeting on the morning of October 12th.



Save the Date

Wake Forest NCORP Research Base 9th Annual Meeting

October 10 - 12, 2022





Healthy Recipe



Peach Cobbler Oatmeal

Prep Time 5 mins Cook Time 5 mins

Makes 4 servings 275 calories per serving

3 1/2 cups water
Pinch of salt
2 1/2 cups rolled oats
2 1/4 tsp cinnamon
Pinch of nutmeg
2 large peaches, chopped
3 to 4 tablespoons light brown sugar
1/4 cup chopped pecans, if desired

Instructions

In a large saucepan over medium heat, add water and salt. Bring to a boil. Add oats, cinnamon, and nutmeg and stir to combine. Cook for 4 minutes, or until oatmeal thickens. Add peaches and brown sugar and cook one additional minute. Serve immediately and garnish with pecans, if desired.





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A program of the National Cancer Institute of the National Institutes of Health

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