**Breast Cancer Clinical Trials at Medical College of Wisconsin/Froedtert Hospital**

**STUDIES OPEN TO ACCRUAL**

**Surgery Trials**

**Medical College of Wisconsin Study #00011003: Postoperative pain control after Mastectomy**  
*Principal Investigator- Dr. Amanda Kong*  
This randomized controlled trial will evaluate pain control after a unilateral mastectomy with or without reconstruction with a local wound catheter, single shot paravertebral block or continuous paravertebral block.

**American College of Surgeons Oncology Group (ACOSOG) Z1071**  
*Principal Investigator- Dr. Tina Yen*  
This phase II trial is studying the role of sentinel lymph node surgery after preoperative chemotherapy in women with known lymph node positive breast cancer (Stage II, IIIA or IIIB) at the time of presentation. All patients will undergo sentinel lymph node biopsy followed by completion axillary lymph node dissection.  

**Medical Oncology Trials**

**Chemotherapy/ Hormonal therapy/Targeted therapy before surgery-**

**American College of Surgeons Oncology Group (ACOSOG) Z1031**  
*Principal Investigator- Dr. Amanda Kong*  
This is a phase III, randomized trial for postmenopausal women with Stage II or III estrogen receptor-positive breast cancer. Eligible patients will be randomized to one of three arms involving 16 to 18 weeks of one of the following Aromatase Inhibitors (AI’s): 1) exemestane 25 mg daily; 2) letrozole 2.5 mg daily; or 3) anastrozole 1 mg daily with the thought that they may make the tumor smaller. Patients will undergo core biopsy after 2-4 weeks of therapy for Ki67 testing. Patients with low Ki67 will continue AI therapy. Patients with high Ki67 will discontinue AI therapy and receive chemotherapy or surgery at physician and patient discretion. All patients are expected to undergo resection of the primary tumor.  

**National Adjuvant Breast and Bowel Project (NSABP) B-40**  
*Principal Investigator- Dr. Alonzo Walker*  
This randomized phase III trial is studying six different chemotherapy regimens to compare how well they work with or without bevacizumab in treating women with stage I, stage II, or stage IIIA, HER2-negative breast cancer. Giving chemotherapy and bevacizumab before surgery may make the tumor smaller and reduce the amount of normal tissue that needs to be removed. Giving bevacizumab after surgery may kill any tumor cells that remain after surgery. It is not yet known which chemotherapy regimen is more effective with or without bevacizumab in treating breast cancer.  
National Adjuvant Breast and Bowel Project (NSABP) B-41

*Principal Investigator- Dr. Alonzo Walker*

The purpose of this randomized phase III study is to determine whether breast cancer tumors respond to combined chemotherapy of AC (doxorubicin and cyclophosphamide) followed by paclitaxel plus trastuzumab or lapatinib or both given before surgery to patients with HER2-positive breast cancer. Trastuzumab will also be given to all patients after surgery.


Chemotherapy/ Targeted therapy after surgery-

**Eastern Cooperative Oncology Group (ECOG) TAILORx/PACCT-1**

*Principal Investigator- Dr. Alonzo Walker*

This randomized phase III trial is trying to find out the best individual therapy for women who have node-negative, estrogen-receptor positive breast cancer by using a special test (Oncotype DX), and whether hormone therapy alone or hormone therapy together with combination chemotherapy is better for women with certain Oncotype DX test results.


**National Adjuvant Breast and Bowel Project (NSABP) B-43**

*Principal Investigator- Dr. Alonzo Walker*

This randomized phase III trial is studying radiation therapy to see how well it works compared with or without trastuzumab in treating women with ductal carcinoma in situ who have undergone lumpectomy.


**National Adjuvant Breast and Bowel Project (NSABP) B-46-I**

*Principal Investigator- Dr. Alonzo Walker*

The main purpose of this randomized phase III study is to learn if adding bevacizumab to standard treatment with chemotherapy (docetaxel, doxorubicin, and cyclophosphamide) for node-positive or high-risk, node-negative, H2N-negative breast cancer will prevent breast cancer from returning.


Psychosocial Research Study-

*Principal Investigator- Rebecca Anderson Ph.D.  Program Coordinator-Kathleen Jensik, MSW*

This research study evaluates an innovative therapeutic approach to stress management and looks at the use of support services with women diagnosed with breast cancer. The intervention is entitled Dialectical Behavior Therapy (DBT) and focuses on mindfulness, interpersonal effectiveness, emotional regulation and distress tolerance. The study will also evaluate trends and satisfaction of support services.

**Contact Information**

To learn more information about the Clinical Trials offered by the Breast Program please contact;

Sandy Welch, Clinical Research Coordinator at 414-805-5831, email: swelch@mcw.edu or Kathleen Jensik, Program Coordinator at 414-805-9001, email: kjensik@mcw.edu

Or Breast Program Surgeons (Dr. Kong, Dr. Walker, Dr. Yen)