

UT CANCER INSTITUTE
CLINICAL TRIALS

JAN/FEB 2012

BREAST

HER2 positive

ACOSOG Z1041 : A Randomized Ph III Trial Comparing a Neoadjuvant Regimen of FEC-75 Followed by Paclitaxel Plus Trastuzumab With a Neoadjuvant Regimen of Paclitaxel Plus Trastuzumab Followed by FEC-75 Plus Trastuzumab in Patients with Palpable and Operable Breast Cancer (Coordinator – Shanna)

Eligibility:

- Dx of adeno carcinoma of the breast by core needle biopsy
- Palpable measurable dz \geq 2 cm
- HER2 positive
- No synchronous lesions
- No surgical axillary staging prior to study start
- No history of invasive breast cancer
- No stage T4 dz

Required Studies:

H&P, weight, height, cardiac hx
within 2 wks-
preg test, CBC w/ diff, plts, creat
bili, AST, Alk Phos
within 3 mos-
EKG, Bone scan, MUGA,
Tumor imaging, liver imaging

SWOG N0733 Randomized Phase II Trial of Capecitabine and Lapatinib with or without IMC-A12 in Patients with HER2 Positive Breast Cancer Previously Treated with Trastuzumab and Anthracycline and/or a Taxane (Coordinator – Shanna)

Eligibility:

- Locally adv. or met. breast ca; progressed after anthracycline and/or taxane and Herceptin
- 1-2 prior regimens in neoadj., adj., or met. setting.
- Measurable disease
- No chemo within 6 weeks prior to start, no RT within 4 weeks of study start
- No prior tx with any agent targeting IGF-I, IGF-II or HER pathway (except Herceptin)

Required Studies:

H&P, weight, height, PS, vitals
Preg test, CBC w/ diff
Chemistry group, fasting glucose
Electrolytes, Lipid profile, INR, UA
CXR or CT, Bone scan, Brain MRI
or CT, EKG, MUGA/ECHO

DCIS : HER2 positive

NSABP B-43 A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2 Positive DCIS Resected by Lumpectomy (Coordinator – Shanna)

Eligibility:

- Females w/ HER2 pos DCIS (determined by central testing)
- Must have received lumpectomy (no mastectomy)
- < 120 out from surgery
- No confirmed microinvasion
- No multicentric DCIS
- No RT prior to study start (no PBI at all)
- No prior treatment or history of breast cancer

Required Studies:

H&P, weight, height, vitals
RT eval (post-op)
Mammogram (within 6 mos)
Preg. Test (within 2 wks)

Node-neg

NCIC MA.32 A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer (Coordinator – Shanna)

Eligibility:

- Invasive breast cancer diagnosed and completed resected within 12 months
- pT1, pT2, pT3; one of pN0, pN1, pN2, pN3; M0
- Must have sentinel node biopsy and/or full axillary lymph node dissection
- No recurrent or metastatic breast cancer
- Cannot be diabetic

Required Studies:

H&P, PS, vitals, height
Hem., Chem., Preg. test
Chest Xray or CT, annual mammogram
Bone Scan if Alk Phos is elevated
QoL questionnaires

Node-pos.

SWOG S1007 A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy with or without Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor Positive and HER2 Negative Cancer with a Recurrence Score of 25 or Less (Coordinator – Shanna)

Eligibility:

- Node positive (1-3 nodes) invasive breast cancer, ER and/or PR positive, HER 2 neg
- Undergone ALND
- No inflammatory or metastatic dz, prior DCIS is ok if rec'd mastectomy alone
- Must have had either breast conserving surgery with planned RT or total mastectomy
- Must have Oncotype no sooner than 28 days and no later than 56 days after definitive surgery

Required Studies:

H&P, PS, vitals, height, weight
Labs, CXR, CT ab, Bone scan, MUGA
Mammo, Oncotype

Partial Breast Irradiation

SAVI A Prospective Phase III Study of the Use of Partial Breast Irradiation (PBI) With the Strut-Adjusted Volume Impact (SAVI™) Breast Brachytherapy Device After Magnetic Resonance Imaging (MRI) of the Breast For Women With Unifocal Stage 0, 1 and Node-negative Stage 2 Breast Carcinoma After Partial Mastectomy, and, in Patients With Invasive Carcinoma, Axillary Sentinel Lymph Node Sampling (Coordinator – Randi)

Eligibility:

- Stage 0, I, or node neg 2 female breast cancer ≤ 3 cm
- Invasive or DCIS
- Partial mastectomy and SLN for invasion
- No axillary nodal dz
- No multifocal or multicentric dz, No known BRCA mutations
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Required Studies:

H&P, med. history
CBC, diff, alk phos, SGOT, SGPT
Mammogram
Ultrasound
MRI, Chest CT

CARCINOID

SWOG S0518: Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab in Advanced Poor Prognosis Carcinoid Patients (Coordinator – Shanna)

Eligibility:

- Unresectable met. or locally adv. low- or intermediate- grade neuroendocrine
- High risk by either a) progressive disease, b) refractory, c) atypical histology
d) met. colorectal carcinoid, e) met. gastric carcinoid
- Must have measurable dz
- Up to 1 prior cytotoxic chemo allowed
- No previous interferon, Avastin or other VEGF drugs

Required Studies: (within 28 days)

H&P, weight, height, BP, PS
CBC, diff, plts, serum creat, bili
SGOT/SGPT, PT, PTT
Serum chromogranin A
Neurospecific enolase
Urinary 5HIAA
CT or MRI, Octreotide scan(recommended)

Gastrointestinal: COLON, RECTAL, STOMACH, HEPATOCELLULAR

Adjuvant colorectal

CALGB 80702: A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer (Coordinator – Shanna)

Eligibility:

- Histologically documented adenocarcinoma of the colon
- Primary tumor must be at least 12 cm from anal verge
- Tumors must have been completely resected with at least one positive node
- No evidence of residual involved lymph node disease or metastatic disease
- Synchronous colon cancers are eligible
- No NSAID use except low dose aspirin not exceeding 100 mg /day

Required Studies:

H&P, weight, height, BSA, vitals, PS
CBC, diff, plts, serum creat, BUN
AST, Alk Phos, Bili, PT/INR
Preg test, CEA
CXR PA & Lateral or Chest CT
Abdominal imaging U/S, CT or MRI

Adv/met. colorectal

CALGB 80405: A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab (C225), or with Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum (Coordinator – Shanna)

Eligibility:

- Histologically or cytologically locally adv. or met. colorectal cancer
- No prior tx for adv. or met. colorectal cancer
- No prior RT to >25% of bone marrow
- Must be at least 4 weeks out since surgery
- No evidence of Gilbert's syndrome for FOLFIRI patients and no grade 2+ sensory peripheral neuropathy for FOLFOX patients

Required Studies:

H&P, weight, height, vitals, PS
CBC, diff, plts, creat, BUN, AST, ALT
Electrolytes, Alk Phos, Bili, Albumin,
LDH, Magnesium, PT/INR, Urinalysis
Chest x-ray
CT scan or MRI

Gastric

SWOG S1005 A Phase II Study of MK-2206 as Second Line Therapy for Advanced Gastric and Gastroesophageal Junction Cancer (Coordinator – Randi)

Eligibility:

- Histologically or cytologically confirmed adeno of stomach or GE junction
- Measurable dz, no brain mets
- No prior tx with PI3, AKT, or MTOR inhibitor for any reason

Required Studies:

H&P, weight, height, vitals, PS
CBC, diff, plts, bili, AST/ALT, INR
Chem 12, Mg, LDH, fasting blood sugar
Hemoglobin A1C, CT or MRI, EKG

HCC

ECOG E1208 A Phase III Randomized, Double-Blind Trial of Chemoembolization with or without Sorafenib in Unresectable Hepatocellular Carcinoma (HCC) in Patients with and without Vascular Invasion (Coordinator – Randi)

Eligibility:

- HCC limited to the liver
- Measurable disease
- Not candidates for curative resection or RFA
- May have undergone previous RFA or resection, but no brachytherapy
- Child-Pugh A or B7

Required Studies:

H&P, vitals, height, weight, PS
CXR and CT or MRI ab/pelvis within 4 wks
CBC w/ diff, chemistry, PT/INR
AFP, preg test

CALGB 80802 Phase III Randomized Study of Sorafenib Plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC) (Coordinator – Randi)

Eligibility:

- HCC, locally advanced or metastatic, measurable disease
- No prior adjuvant therapy with Nexavar or other Raf/VEGFR drugs
- No prior systemic tx for metastatic dz

Required Studies:

H&P, vitals, height, weight, PS
EKG, MUGA or ECHO, CT scan/MRI
CBC, diff, plts, creat, BUN, electrolytes
Glucose, AST/ALT, Alk Phos, Albumin
Hep B, Hep C, PT/INR, AFP, preg test

GENITOURINARY

Deleted: ¶

Renal Advanced/Met.

CALGB 90802 Randomized Phase III Trial Comparing Everolimus Plus Placebo Versus Everolimus Plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment with Tyrosine Kinase Inhibitors (Coordinator – Randi)

Eligibility:

- Renal cell with some component of clear cell histology
- Metastatic or unresectable
- Must have received at least 1 prior VEGFR treatment and progressed
- No prior treatment with Avastin or Torisel (no VEGF or mTOR)
- Prior cytokine tx allowed
- Must have measurable disease

Required Studies:

H&P, vitals, weight, PS
CBC, diff, plts, creat, LDH, albumin, glucose
AST, ALT, Alk phos, Bili, Preg. test
Triglycerides, cholesterol, HBV/DINA testing
UPC ratio
Brain MRI or CT, CT/MRI chest, ab, pelvis,
Bone scan

SWOG S0931 EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study (Coordinator – Randi)

Eligibility:

- Histo or cyto confirmed renal cell (clear or non-clear cell allowed)
- Collecting duct or medullary carcinomas excluded
- Must be considered pathologically intermediate High Risk or Very High Risk
- Must have undergone a full surgical resection including removal of clin pos nodes
- Bilateral renal tumors are eligible if both have full surgical resection
- No evidence of residual or met dz on CT
- No prior anti-cancer therapy for renal cell carcinoma
- No systemic corticosteroids or other immunosuppressive agents

Required Studies:

H&P, vitals, weight, PS
Hep B/C screening
WBC, diff, plts, bili, SGOT, SGPT
Creatine, alk phos
Fasting glucose, cholesterol, triglycerides
CT of chest/ab/pelvis
Bone scan (if rising alk phos or bone pain)

GYNECOLOGIC

GOG-0262 A Randomized Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel in Combination with Carboplatin with or without Concurrent and Consolidation Bevacizumab in the Treatment of Primary Stage III or IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer (Coordinator – Randi)

Eligibility:

- Histologic dx of epithelial ovarian cancer, fallopian tube, or peritoneal primary
- FIGO stage III with more than 1 cm residual or FIGO stage IV
- Must enroll within 12 wks of diagnostic/staging surgery
- No prior RT to ab or pelvis
- No prior chemo for ab or pelvis tumor
- No prior targeted therapy or hormonal therapy for management of GYN cancer

Required Studies:

H&P, BP, EKG, QofL assessment
CBC, diff, plts, UA, UPC ratio, creat.
Bili, SGOT, Alk Phos, Ca/PO4/Mg
Serum preg test, PT/INR, PTT
Audiogram, CA-125
CT/MRI of ab and pelvis, CXR

GOG-0249 A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Carcinoma (Coordinator – Randi) **Temporarily Closed**

HEAD and NECK

ECOG 1305 A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients With Recurrent or Metastatic Head and Neck Cancer (Coordinator – Randi)

Eligibility:

- Squamous cell H&N from any primary site, no nasopharyngeal ca
- Must be recurrent or metastatic
- No prior chemo or targeted therapy for recurrent or met. dz
- Previous palliative RT is allowed
- Measurable dz

Required Studies:

History/physical, PS, height, weight
CBC, diff, plts, creatinine, electrolytes
Calcium, Mg, liver function tests, PT/PTT
UPC (after baseline, Arm B only)
CT chest and neck, EKG

LEUKEMIA/ LYMPHOMA/ MULTIPLE MYELOMA

Leukemia

ECOG E1908 A Phase II Randomized Trial Comparing Standard and Low Dose Rituximab: Initial Treatment of Progressive Chronic Lymphocytic Leukemia in Elderly Patients Using Alemtuzumab and Rituximab (Coordinator – Shanna)

Eligibility:

- CLL (see protocol for info regarding lymphocyte count and phenotype)
- No previous tx for CLL
- Must be progressive as defined by protocol

Required Studies:

H&P, weight, height, PS
Hem, Chem, DAT for IgG and C3
CMV DNA by PCR, Hep B&C
CT, Bone marrow biopsy/aspirate and cyto

Hodgkins Lymphoma

CALGB 50604 Phase II Trial of Response-Adapted Chemotherapy Based on PET for Non-Bulky Stage I and II Hodgkin Lymphoma (Coordinator – Shanna) **ON HOLD**

Eligibility:

- Stage IA, IB, IIA, IIB classical Hodgkin lymphoma
- Nodular lymphocyte predominant is excluded
- No prior tx for HL
- Measurable disease

Required Studies:

H&P, height, weight, BSA, PS
CBC, diff, plts, ESR, creat, glucose, LDH
AST, Alk phos, bili
LVEF by ECHO or MUGA, PFTs, preg test

Multiple Myeloma

ECOG E3A06 Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma (Coordinator – Shanna) **ON HOLD**

Eligibility:

- Dx of asymptomatic smoldering MM within past 12 months
- Measurable levels of monoclonal protein (see protocol for details)
- No lytic lesions and no hypercalcemia
- No prior or concurrent systemic or RT for tx of myeloma
- No prior use of glucocorticosteroid for tx of MM

Required Studies:

H&P, PS, weight, vitals
 Bone marrow aspirate and biopsy
 Chem, CBC w/diff, light chain assay
 Immnoglobulin G, A, M, SPEP, M-protein
 24 hr urine, bone survey, ECG, preg test
 Beta 2 microgl, C-reactive prot, LDH, TSH
 MRI (spine and pelvis)

LUNG

Adjuvant

SWOG S0720 Phase II ERCC1 and RRM1-Based Adjuvant Therapy Trial in Patients with Stage I NSCLC (Coordinator – Randi)
temporarily closed

Eligibility:

- Resected Stage IA (≥ 2 cm) or Stage IB NSCLC
- Tumor tissue sent out for gene expression analysis
- No prior tx other than surgery for NSCLC

Required Studies:

H&P, PS, weight, vitals
 CT of chest/ab
 Whole PET or PET/CT
 ANC, Plt, Hgb, Bili, SGOT/SGPT, CrCl

CALGB 140503 A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (≤ 2 cm) Peripheral NSCLC (Coordinator – Randi) **NOTE:** Contains imaging substudy CALGB 580602

Eligibility:

- Peripheral lung nodule ≤ 2 cm on CT and presumed to be lung cancer
- Tumor location suitable for lobar or sublobar resection
- No prior malignancy within 5 yrs
- No prior chemo or RT for this malignancy
- No evidence of locally advanced or met. dz
- **Intraoperatively:** histologic confirmation of NSCLC, and N₀ status
- **NOTE:** Randomization is done intra-operatively

Required Studies:

Phy. Exam, PS
 Pulmonary function tests
 CXR
 Chest CT or PET/CT within 42 days

ECOG E1505 A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients with Completely Resected Stage IB (≥ 4 cm) – IIIA NSCLC (Coordinator – Shanna)

Eligibility:

- Complete resection of T2-3N0, T1-3N1, T1-3N2 NSCLC
- If tumor is stage IB, must be at least 4 cm in size
- 6-12 weeks post-thoracotomy
- No prior systemic chemo, hormonal tx, or RT (unless more than 5 yrs)

Required Studies:

H&P, PS, weight, BP
 Chem, CBC, PT/INR/PTT
 UPC
 CXR, CT, smoking status survey

Adv./Met.

SWOG S0819 A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced NSCLC (Coordinator – Randi)

Eligibility:

- Histo or cyto confirmed stage IV NSCLC
- Measurable or nonmeasurable dz
- No prior chemo or targeted EGFR tx
- Prior RT is ok

Required Studies:

H&P, height, weight, PS, EKG
 CBC, diff, plts, creatinine and creat clear.
 UPC, total bili, SGOT or SGPT, Alk Phos
 INR, albumin, LDH, sodium, calcium, mag
 Brain CT or MRI, Bone Scan (if clin indicat)

Amgen A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Long-Term Safety and Efficacy of Darbepoetin Alfa Administered at 500 mcg Once Every 3 Weeks in Anemic Subjects with Advanced Stage NSCLC Receiving Multi-Cycle Chemotherapy **Pending**

BiPar Sciences Randomized Phase 3 Trial of Gemcitabine/Carboplatin With or Without BSI-201 (a PARP1 Inhibitor) in Patients with Previously Untreated Advanced Squamous Cell Lung Cancer (Coordinator – Shanna)

Eligibility:

- Newly diagnosed stage IV squamous NSCLC
- Prior adj tx allowed if >12 mos
- Previous RT allowed if outside original RT port
- Measurable or non-measurable dz
- No prior tx with Gemzar, carboplatin (except adj setting), or iniparib

Required Studies:

H&P, vitals, height, weight, PS
CBC, diff, plts, CMP, serum preg test
CT (chest/ab), CT or MRI of brain
PET scan or bone scan

Small Cell

CALGB 30610 Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited SCLC Also Receiving
RTOG 0538 Cisplatin and Etoposide (Coordinator – Randi)

Eligibility:

- Histo or cyto confirmed SCLC
- Limited stage dz, no complete resection
- Measurable dz
- No prior treatment for SCLC

Required Studies:

H&P, vitals, height, weight, PS
CBC, diff, plts, bili, LDH, AST, Cr., BUN
Mg, Na, Ca
Bone or PET scan, DLCO, FEV-1, FVC
CT chest, ab and MRI or CT of brain

SWOG S0802 A Randomized Phase II Trial of Weekly Topotecan with and without AVE0005 (Aflibercept; NSC-724770) in Patients with Platinum Treated Extensive Stage Small Cell Lung Cancer (E-SCLC) Study (Coordinator – Randi)
ONLY PLATINUM SENSITIVE IS OPEN (Refractory is closed)

Eligibility:

- Extensive stage small cell lung cancer
- Progression or recurrence after ONE standard first-line platinum tx
- Stable brain mets ok
- No prior Avastin or anti-angiogenic tx

Required Studies:

H&P, weight, PS, BP
CBC, diff, UPC, PT/INR, PTT
Brain CT or MRI
Bone scan if clin. indicated

MELANOMA

ILI-Lewis Isolated Limb Infusion (ILI) with Melphalan and Actinomycin-D for Recurrent and In-transit Extremity Melanoma (Coordinator – Shanna)

Eligibility:

- Stage IIIB, IIIC, limited stage IV dz to an extremity
- Palliative ILI will be considered for pain control/limb salvage

Required Studies:

H&P, vitals
CT/MRI
FACT M, FACT G evals

JWCI Multicenter Selective Lymphadenectomy Trial II (MSLT-II): A Phase III Multicenter Randomized Trial of Sentinel Lymphadenectomy and Complete Lymph Node Dissection versus Sentinel Lymphadenectomy Alone in Cutaneous Melanoma Patients with Molecular or Histopathological Evidence of Metastases in the Sentinel Node (Coordinator – Shanna)

Eligibility:

- Tumor-positive SN by H&E or IHC or RT-PCR analysis
- Primary melanoma (see protocol for breakdown)
- No previous or concurrent invasive melanoma

Required Studies:

Nodal US and CXR within 30 days
Chest CT within 90 days, QofL survey
H&P, PS, vitals, height, weight

PANCREATIC

Adjuvant

ACOSOG A Phase II Study of Preoperative Gemcitabine and Erlotinib Plus Pancreatectomy and Postoperative Gemcitabine and
Z5041 Erlotinib for Patients with Operable Pancreatic Adenocarcinoma (Coordinator – Shanna)

Eligibility:

- Adeno of the pancreatic head or uncinate process
- NO neck, body or tail pancreatic cancer
- Locally potentially resectable tumors

Required Studies:

H&P, PS, vitals, height, weight, BSA
Smoking hx, CBC w/ diff, electrolytes, BUN
creat., glucose, calc., album., total protein

- a) no tumor extension to the celiac axis, hep. artery or sup. mesenteric artery
- b) no encasement or occlusion of the SMV or SMV/portal vein confluence
- c) no evidence of visceral or peritoneal mets

SGOT, SGPT, Alk phos, total bili, CA 19-9
PT/INR/PTT, preg test
CXR or chest CT, ab CT

Advanced/Metastatic

CALGB 80701 Randomized Phase II Study of Everolimus Alone Versus Everolimus Plus Bevacizumab in Patients with Locally Advanced or Metastatic Pancreatic Neuroendocrine Tumors (Coordinator – Shanna)

Eligibility:

- Histo confirmed well or mod. diff pancreatic neuroendocrine tumor
- Locally unresectable or metastatic
- No prior tx with Avastin, Torisel or other mTOR inhibitors
- Measurable or non-measurable dz with evidence of progression
- Prior embolization or ablation ok if measurable dz remains

Required Studies:

H&P, PS, vitals, height, weight
CBC, diff, plts, bili, ALT/AST, albumin,
Alk phos, total protein, glucose, BUN, creat
Electrolytes, Uric acid, urine protein, lipids
Preg test, chromogranin A, Hep A and B,
HBV DNA testing, CT scan chest/ab/pelvis

PROSTATE

Met. Prostate

ECOG E3805 ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer
CHAARTED (Coordinator – Randi)

Eligibility:

- Prostate cancer patients. If hormonal tx has begun, it must not be > 120 days
- Metastatic dz
- Just have discontinued hormonal tx in adj. setting 12 mos prior to study entry Total bili

Required Studies:

H&P, vitals, CBC, diff, plts
Creatinine clearance, PTT, PT, INR
ALT (Arm A), PSA, Bone scan
CT ab/pelvis, CXR or CT chest

SARCOMA

J&J SAR3007 A Randomized Controlled Study of YONDELIS (Trabectedin) or Dacarbazine for the Treatment of Advanced Liposarcoma or Leiomyosarcoma Previously Treated With an Anthracycline and Ifosfamide (Coordinator – Shanna)

Eligibility:

- Histologic proven, unresectable, locally adv or met liposarcoma or leiomyosarc
- Treated w an anthracycline and ifosfamide
- Measurable dz
- No prior trabectedin or dacarbazine

Required Studies:

H&P, vitals, BSA, ECOG ps
Chem, Hem, liver panels, preg test
ECHO or MUGA, ECG
CT or MRI of chest/ab/pelvis

MISCELLANEOUS

ODAM O DAM as a Novel Biomarker of Human Breast Cancer (Coordinator – Randi)

Eligibility:

- Breast cancer patients scheduled to receive surgery.
- Willingness of patient have extra tube of blood drawn prior to surgery (at pre-op visit) and again 26 & 52 wks after surgery

QUESTIONS REGARDING PROTOCOLS Call the Clinical Trials Office at (865) 305-9773