ACTIVE CANCER CLINICAL TRIALS
January 2013

Clinical Trials Nurses
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Additions:

• RTOG 1203 – Standard vs IMRT pelvic RT for post-operative treatment of endometrial and cervical cancer

Changes:

• CALGB-50303 – PET/CT credentialing completed. Trial is available for accrual.
• ECOG E6508 – No longer suspended
• ECOG E7208 – Planned suspension for review

Closures:

• CALGB 80701 – Closed to accrual (pancreatic)
• ECOG E2208 – Closed to accrual (metastatic esophageal or GEJ)

BREAST CANCER

HER2+ invasive breast cancer with brain mets.......................................................... RTOG-1119
WBRT vs WBRT + oral lapatinib

Newly diagnosed, stage 0-IIIA, post-lumpectomy, -quadrantectomy, or -mastectomy, will receive RT .......... CTSU WFU-97609
Impact of Genomics and Exposures on Disparities in Breast Cancer Radiosensitivity
Labs, questionnaires, and optional photographs

Node-positive or high-risk node-negative HER2-negative........................................................................ NSABP B-49
Investigator choice:
TAC or AC→WP or DD AC→WP or DD AC→DD P

vs
TC

Early-stage resected by lumpectomy.......................................................................................... RTOG-1005

IRB review pending -- Can be expedited upon request.
Standard fractionation vs Hypofractionation (15 fractions total)
Whole breast 50.0 Gy/25 fractions/2.0 Gy daily Whole breast 40 Gy/15 fractions/2.67 Gy daily
Optional fractionation of 42.7 Gy in 16 fractions Concurrent boost 48.0 Gy/3.2 Gy daily
Sequential Boost 12.5 Gy/6 fractions/2.0 Gy daily or 14.0 Gy/7 fractions/2.0 Gy daily

Resected node-positive or high-risk node-negative HER2-Low Invasive ................................ NSABP B-47

IRB review pending -- Can be expedited upon request.
Physician choice of chemo:
TC or AC→ weekly paclitaxel then chemo vs chemo + (trastuzumab for 1 yr)

GASTROINTESTINAL MALIGNANCIES - ESOPHAGEAL

Advanced or metastatic adenocarcinoma of esophagus, gastric or GEJ........................................... CTSU S1201

IRB review pending -- Can be expedited upon request.
Low or High-ERCC1: FOLFOX vs docetaxel + irinotecan
Esophageal cancer treated without surgery; \( \geq 18 \) and \(< 75 \) yrs of age, squamous only..........................CTSU RTOG-0436

RT + Paclitaxel + Cisplatin + Cetuximab \( \text{vs} \) RT + Paclitaxel + Cisplatin

Her2-Positive, adenocarcinoma of esophagus involving mid, distal and/or esophagogastric junction ........................................... RTOG 1010

**IRB review pending -- Can be expedited upon request.**

Must send out ICH

RT + paclitaxel + carboplatin + trastuzumab \( \text{then} \) sy 5-8 wks after RT \( \text{then} \) trastuzumab q3wk x 13

vs

RT + paclitaxel + carboplatin \( \text{then} \) sy 5-8 wks after RT

**GASTROINTESTINAL MALIGNANCIES - STOMACH**

Advanced or metastatic adenocarcinoma of esophagus, stomach or GEJ ..........................................................CTSU S1201

**IRB review pending -- Can be expedited upon request.**

Low or High-ERCC1: FOLFOX \( \text{vs} \) docetaxel + Irinotecan

**GASTROINTESTINAL MALIGNANCIES – COLON**

Resected stage I or II colon cancer ........................................NSABP P-5

Rosuvastatin 10mg once daily x 5 years \( \text{vs} \) Placebo taken once daily x 5 years

Advanced, K-ras wild-type colorectal ca after progression on bevacizumab-containing chemo - Phase II ...................ECOG E7208

Suspended 6-14-2012

**IRB review pending -- Can be expedited upon request.**

Must have had prior first-line with oxaliplatin-based 5-FU chemo + bevacizumab for metastatic colorectal cancer

Irinotecan + Cetuximab every 2 wks \( \text{vs} \) Irinotecan + Cetuximab + Ramucirumab (IMC-1121B) every 2 wks

**GENITOURINARY – RENAL**

Advanced renal cell carcinoma progressing after tx with tyrosine kinase inhibitors ..............................CTSU CALGB-90802

Everolimus \( \text{vs} \) Everolimus + Bevacizumab

**GENITOURINARY – BLADDER**

Metastatic or unresectable transitional cell carcinoma of urinary tract .............................................CALGB 90601

Gemzar + Cisplatin + Placebo \( \text{vs} \) Gemzar + Cisplatin + Bevacizumab

Muscle-invasive bladder cancer, non-cystectomy candidates, Phase I/II ...........................................CTSU RTOG-0524

**Her2/neu overexpression:**

RT + Paclitaxel + Trastuzumab

**No her2/neu overexpression:**

RT + Paclitaxel

**GYNECOLOGIC – CERVICAL or ENDOMETRIAL**

***Hysterectomy, requires post-op RT or chemoRT ............................................................. RTOG 1203

**IRB review pending -- Can be expedited upon request**

IMRT pelvic RT \( \text{vs} \) 4-field pelvic RT

**HEAD AND NECK**

HPV-associated oropharynx \( T_{1,2}N_{0-3a}, T_{3,4} \text{any } N \) ......................................................... RTOG 1016

**IRB review pending -- Can be expedited upon request**

Mandatory p16 analysis by OSU lab after pt. consent & before randomization

IMRT + high dose cisplatin \( \text{vs} \) IMRT + cetuximab

\( x6 \) wks \( \text{d } 1,22 \text{ x6wks} \)

\( x6 \) wks \( 8 \) doses (1 prior to chemoXRT & 1 following chemoXRT)
Locally-advanced resected head and neck cancer -- *Gross total resection of tumor; no prior chemo* ............................................. RTOG 0920  
*T1, N1-2 or T2-4a, N0-2, M0*

RT (2 Gy/day, in 30 fractions for total of 60 Gy)  
vs  
Cetuximab  
then  
RT (as above)  
Cetuximab  
(250 mg/m²/week x 6)  
Cetuximab  
(250 mg/m²/week x 4)

Recurrent or metastatic head and neck, performance status 0 or 1 ................................................................. ECOG E1305

Physician choice of chemotherapy regimens  
Platinum-doublet  
vs  
Platinum-doublet + Bevacizumab

MDS

Higher risk MDS  
*IRB review pending -- Can be expedited upon request* ................................................................. CTSU S1117

Azacitidine + Lenalidomide  
vs  
Azacitidine  
vs  
Azacitidine + Vorinostat

Low- or Intermediate-1 Risk MDS and Symptomatic Anemia ................................................................. ECOG E2905

Del 5q31.1:  
Arm A -- Lenalidomide until relapse/progression/no MER  
then  
cross over to Arm B

Not Del 5q3.1:  
Arm A -- Lenalidomide until relapse/progression/no MER  
then  
cross over to Arm B  
or  
Arm B -- Lenalidomide + epoetin alfa until relapse/progression

LEUKEMIA

Higher risk CMML  
*IRB review pending -- Can be expedited upon request* ................................................................. CTSU S1117

Azacitidine + Lenalidomide  
vs  
Azacitidine  
vs  
Azacitidine + Vorinostat

Previously treated relapsed or refractory chronic lymphocytic leukemia  
*Phase II* ................................................................. ECOG E2903

*IRB review pending -- Can be expedited upon request*  
Rituximab + Pentostatin + Cyclophosphamide  
then  
if complete or nodular partial remission:  
Campath-1H (30 mg sc TIW x 4 wks)  
or  
if partial remission or less than partial remission or progressive disease:  
Campath-1H (30 mg sc TIW x 18 wks)

LYMPHOMA

Untreated diffuse large B-cell lymphoma -- *fresh (frozen) tumor biopsy must be available* ........................................ CTSU CALGB-50303  
R-CHOP  
vs  
DA-EPOCH-R

Untreated early-stage diffuse large B-cell lymphoma ................................................................. CTSU S1001  
*IRB review pending -- Can be expedited upon request*  
R-CHOP  
then  
PET negative - R-CHOP x1  
or  
PET positive - IFRT then Zevalin

High risk follicular lymphoma ................................................................. ECOG E2408  
*IRB review pending -- Can be expedited upon request*  
Rituximab + Bendamustine x 6 cycles  
then  
Rituximab  
vs  
Rituximab + Bendamustine + Bortezomib x 6 cycles  
then  
Rituximab  
vs  
Rituximab + Bendamustine  
then  
Lenalidomide + Rituximab
MELANOMA

High risk completely resected melanoma - no prior adjuvant tx ..................................................... ECOG E1609

IRB review pending - Can be expedited upon request

Randomize within 84 days of resection

Ipilimumab then maintenance vs Interferon Alfa-2b then maintenance vs Ipilimumab then maintenance

(10mg/kg) qwk x 4
(q3wks x 4)

THORACIC - SMALL CELL or NON-SMALL CELL LUNG CANCER

Treated with chemo + RT for small cell or NSCLC -- Phase II Suspended ............................................. RTOG 1012

3dCRT only

Standard supportive care
vs
Liquid Manuka honey 4x/day
vs
Manuka honey lozenges 4x/day

THORACIC - NON-SMALL CELL LUNG CANCER

Unresectable Stage IIIA/B non-squamous NSCLC without significant pleural effusion -- Phase II .................. ECOG E6508

Paclitaxel + Carboplatin for 2 cycles + RT for 6.5 wks
then if no disease progression
Paclitaxel + Carboplatin for 2 cycles
then if no disease progression
Cyclophosphamide + Bevacizumab + L-BLP25 vaccine up to maximum of 34 cycles

NSCLC and N0 -- <2cm peripheral & outer third ................................................................. CTSU CALGB-140503

Lobectomy vs Limited Resection

Completely resected stage IB-IIIA NSCLC ................................................................. ECOG E1505

Physician choice of: cisplatin + (vinorelbine, docetaxel, gemcitabine, or pemetrexed)
vs
Physician choice of the above therapies + Bevacizumab

Advanced non-squamous NSCLC ................................................................. ECOG E3508

Paclitaxel + Carboplatin + Bevacizumab on day 1 of 6 cycles then if no PD Bevacizumab until PD
vs
Paclitaxel + Carboplatin + Bevacuzumab + IMC-A12 x 6 cycles then if no PD Bevacizumab + IMC-A12 until PD
(d1) (d1) (d1) (d 1,8,15)

Advanced non-squamous NSCLC ................................................................. ECOG E5508

Paclitaxel + Carboplatin + Bevacizumab on day 1 of 4 cycles
then
Bevacizumab vs Pemetrexed vs Bevacizumab + Pemetrexed

***Denotes newly activated study