ACTIVE CANCER CLINICAL TRIALS
April 2014

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Changes:
• ECOG E1609 – Melanoma, Arm A closed to accrual

2014 Trial Accrual  
Reminder: ECOG-ACRIN credit goal is 6 patients a year, NRG is 3 patients a year.

Awaiting our first accrual for 2014!

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BREAST CANCER

T1-3, N1 breast cancer, positive axillary nodes by FNA or core needle bx .................................. NSABP B-51/RTOG 1304

IRB review pending -- Can be expedited upon request.

Preferred: Minimum 12 wks of neoadjuvant consisting of anthracycline and/or taxane plus anti-HER2 for HER2+ tumors but if adjuvant after surgery, a max of 12 wks needs completed.

If Lumpectomy:
- WBI + boost vs WBI + boost and regional nodal irradiation

If Total Mastectomy:
- No RT vs Chest wall and regional nodal irradiation

Stage I-III breast cancer receiving anastrozole, Asian or African American only .................................. ECOG E1Z11

Anastrozole then No AIMSS: f/u q3 mos, with PRO, up to 1 yr

1mg daily

AIMSS: treatment at discretion of physician
Continue/discontinue drug, treat AIMSS, ≤ 6 wk holiday, switch AI, tamoxifen, or treatment trial
If discontinuation, PRO, then f/u 1 mo, PRO

HER2+ invasive breast cancer with brain mets .......................................................... RTOG-1119

WBRT vs WBRT + oral lapatinib

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 12.7 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)

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

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 then sy 5-8 wks after RT then trastuzumab q3wk x 13
- vs
- RT + paclitaxel + carboplatin then sy 5-8 wks after RT

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 vs docetaxel + Irinotecan
**PANCREATIC**

Distant metastatic disease .............................................................................................................................................. CTSU S1115

2nd line – Phase II, must have received gemcitabine 1st line

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

mFOLFOX vs MK-2206 + AZD6244 hydrogen sulfate

**COLON**

Any stage newly dx colorectal adenocarcinoma with dx in 2013-2014 .............................................................................. OSU OCCPI

Tissue submission for MSI + IHC +/- methylation -- screening for Lynch Syndrome

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 vs Irinotecan + Cetuximab + Ramucirumab (IMC-1121B) every 2 wks

**BLADDER**

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

**CERVICAL or ENDOMETRIAL**

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

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

IMRT pelvic RT vs 4-field pelvic RT

**HEAD AND NECK**

Phase II/III Stage III/IV HNSCC ........................................................................................................................................ RTOG 1216

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

All pts – tissue submission for EGFR; if oropharyngeal, p16 analysis -- both after consent & before randomization

IMRT + cisplatin vs IMRT + docetaxel vs IMRT + docetaxel + cetuximab

x6 wks 40mg/m² x6 x6 wks 15mg/m² x6 x6 wks 15mg/m² x6 loading 400mg/m² then 250mg/m² x6

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 then Cetuximab

(initial dose 400 mg/m²) (250 mg/m²/week x 6) (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

Persistent lymph node disease following primary concurrent chemoRT for Stage III/IV HNSCC of oral cavity, oropharynx, larynx, or hypopharynx, **Phase II** ......................................................................................................................... ECOG E1311

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

Afatinib (40mg PO or G-tube QD x 12 cycles) vs Placebo (PO or G-tube QD x 12 cycles)
**MDS**

Higher risk MDS

Physician must take lenalidomide training, perform birth control portion of consent, re-counsel at least every 28 days

IRB review pending -- Can be expedited upon request

Azacitidine + Lenalidomide  vs  Azacitidine  vs  Azacitidine + Vorinostat

Low- or Intermediate-1 Risk MDS and Symptomatic Anemia

Physician must take lenalidomide training, perform birth control portion of consent, re-counsel at least every 28 days

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

Physician must take lenalidomide training, perform birth control portion of consent, re-counsel at least every 28 days

IRB review pending -- Can be expedited upon request

Azacitidine + Lenalidomide  vs  Azacitidine  vs  Azacitidine + Vorinostat

**LYMPHOMA**

Untreated early-stage diffuse large B-cell lymphoma

R-CHOP

then

PET negative - R-CHOP x1  or  PET positive - IFRT then Zevalin

Newly Dx diffuse large B-cell lymphoma, Phase II

Lenalidomide + R-CHOP  vs  RCHOP

High risk follicular lymphoma

Physician must perform birth control portion of consent

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

Mandatory enrolling investigator training for ipilimumab prior to patient enrollment
Randomize within 84 days of resection ---- Arm A closed to accrual

Ipilimumab then maintenance vs Interferon Alfa-2b then maintenance vs Ipilimumab then maintenance
(10mg/kg) qwk x 4 (3mg/kg) q3wks x 4

Unresectable stage III or IV melanoma of cutaneous or unknown primary origin, histologically diagnosed.............ECOG E3611

1st line or recurrent – Phase II

Mandatory investigator training for ipilimumab prior to patient enrollment
IRB review pending -- Can be expedited upon request

Ipilimumab + Interferon then maintenance Ipilimumab + Interferon
(10mg/kg) (10mg/kg)
q3wks x 4 q12wks – max 4 doses

vs

Ipilimumab then maintenance Ipilimumab
(10mg/kg) (10mg/kg)
q3wks x 4 q12wks – max 4 doses

vs

Ipilimumab + Interferon then maintenance Ipilimumab + Interferon
(3mg/kg) (3mg/kg)
q3wks x 4 q12wks – max 4 doses

vs

Ipilimumab then maintenance Ipilimumab
(3mg/kg) (3mg/kg)
q3wks x 4 q12wks – max 4 doses

MULTIPLE MYELOMA

Newly dx symptomatic multiple myeloma – Phase II .................................................................ECOG E1A11

Physician must perform birth control portion of consent.

Induction:

Bortezomib + Lenalidomide + Dexamethasone (q 3wks x 12) vs Carfilzomib + Lenalidomide + Dexamethasone (q 4wks x 9)
1.3mg/m² SQ or IV 25mg PO PO 20mg/m²IV cycle 1 25mg PO PO
then

Maintenance:

Lenalidomide (q 4 wks x 24) then observation vs Lenalidomide (q 4wks) until progression or excessive toxicity
15mg PO 15mg PO
LUNG - NON-SMALL CELL LUNG CANCER

EGFR Wild-Type, Stage IV NSCLC incl M1a, M1b, or recurrent disease – Phase II..............................................................ECOG E1512
2nd or 3rd line
Erlotinib (150mg po daily) vs Cabozantinib (60mg po daily) vs Cabozantinib (40mg PO daily) + Erlotinib (150 mg PO daily)
at progression, may opt for Cabozantinib (40mg po daily) + Erlotinib (150mg po daily)

Unresectable Stage IIIA/B non-squamous NSCLC without significant pleural effusion -- Phase II........................................ECOG E6508
Paclitaxel + Carboplatin for 2 cycles + RT x 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

Advanced non-squamous NSCLC .................................................................................................................................................ECOG E5508
Paclitaxel + Carboplatin + Bevacizumab on day 1 of 4 cycles
then
Bevacizumab vs Pemetrexed vs Bevacizumab + Pemetrexed

LUNG - SMALL CELL LUNG CANCER

Extensive SCLC – Phase II .......................................................................................................................................................ECOG E2511
Veliparib + Etoposide + Cisplatin for 4 cycles vs Placebo + Etoposide +Cisplatin for 4 cycles
100mg bid days 1-3 day 1
100mg bid days 1-7 day 1

Unresectable Stage IIIA/B non-squamous NSCLC – Phase II .................................................................................................RTOG 1306
IRB review pending -- Can be expedited upon request
EGFR TK Mutation Cohort:
Erlotinib(150 mg/day x 12 wks) then Standard Chemo*/RT vs Standard Chemo*/RT
ALK Tran L Cohort or EGFR + ALK Tran L:
Crizotinib (250 mg/bid x 12 wks) then Standard Chemo*/RT vs Standard Chemo*/RT
*Standard ChemoChoice: cisplatin +etoposide or paclitaxel + carboplatin

***Denotes newly listed study