ACTIVE CANCER CLINICAL TRIALS
May 2011

If you would like to speak with a research nurse please call one of the following:

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Changes made since previous listing:

Additions:
  • NSABP B47 (Breast - Page 2) - Will request IRB approval upon presentation of eligible patient
  • ECOG E2408 (Lymphoma - Page 4) - Will request IRB approval upon presentation of eligible patient
  • RTOG 1010 (Esophageal - Page 2) - Will request IRB approval upon presentation of eligible patient
  • CALGB 90601 (Bladder - Page 3) - Open to accrual

Changed:
  • ECOG E1608 (Page 4) - Each enrolling investigator is required to review the slide deck entitled: *E1608 Ipilimumab Immune Related Adverse Events: Summary and Recommended Management* and complete the associated quiz prior to their first patient enrollment.
  • CALGB 40502 (Page 2) - Physician choice if bevacizumab is added to treatment.

Closures:
  • RTOG 0825 - Phase III Double-blind Placebo-controlled Trial of Conventional Concurrent Chemoradiation and Adjuvant Temozolomide Plus Bevacizumab versus Conventional Concurrent Chemoradiation and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma
    *Per RTOG:* “…study has met its accrual objective.”
BREAST CANCER

***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→WP
then chemo vs chemo + (trastuzumab for 1 yr)

Locally recurrent or metastatic, first-line................................................................................................................................. CALGB-40502

Physician option to add bevacizumab to any of the treatments
Paclitaxel vs Nab-paclitaxel vsIxabepilone

Node positive or node negative > 1cm ................................................................................................................................. CTSU N063D

Physician choice: Paclitaxel or Docetaxel or Docetaxel + Carboplatin with randomization to: ALITTO TRIAL

Trastuzumab alone for 1 yr
vs
Lapatinib alone for 1 yr
vs
Trastuzumab for 12 wks then 6-wk break then lapatinib for 34 wks
vs
Trastuzumab + lapatinib for 1 yr

Node positive or node negative > 2cm or high risk per investigator discretion (pre or post menopausal) ...................... CTSU S0221

≤ 84 days from mastectomy, axillary dissection or sentinel node detection
Adriamycin/Cytoxan + Pegfilgrastim (q 2 wks x 4) then Taxol + Pegfilgrastim (q 2 wks x 6)
(60mg/m²) (600mg/m²) (175mg/m²)
vs
Adriamycin/Cytoxan + Pegfilgrastim (q 2 wks x 4) then Taxol (q wk x 12)
(60mg/m²) (600mg/m²) (80mg/m²)

HER2-Positive invasive breast cancer diagnosed by core needle biopsy, palpable mass ≥ 2.0 cm .............................................. NSABP B-41

IRB review pending -- Can be expedited upon request.

Paclitaxel + Trastuzumab

AC then Paclitaxel + Lapatinib then Surgery then Trastuzumab
then Paclitaxel + Trastuzumab + Lapatinib

GASTROINTESTINAL MALIGNANCIES - ESOPHAGEAL

Esophageal cancer treated without surgery; ≥ 18 and < 75 yrs of age ............................................................... CTSU RTOG-0436
RT + Paclitaxel + Cisplatin + Cetuximab vs RT + Paclitaxel + Cisplatin

Second-line treatment for metastatic esophageal or GE junction .................................................................................. ECOG E2208
Paclitaxel vs Paclitaxel + Cixutumumab

***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
GASTROINTESTINAL MALIGNANCIES – COLON

Resected stage I or II colon cancer ................................................................. NSABP P-5
  Rosuvastatin 10mg once daily x 5 years 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
  Must have had prior first-line with oxaliplatin-based 5-FU chemo + bevacizumab for metastatic colorectal cancer
IRB review pending -- Can be expedited upon request.
  Irinotecan + Cetuximab every 2 wks vs Irinotecan + Cetuximab + Ramucirumab (IMC-1121B) every 2 wks

GASTROINTESTINAL MALIGNANCIES – COLON OR RECTUM

Metastatic colon or rectum, KRAS normal (wild type) only ................................................................. CTSU CALGB-80405
  Bevacizumab then FOLFOX or FOLFIRI (investigator’s choice)
vs
  Cetuximab then FOLFOX or FOLFIRI (investigator’s choice)

GENITOURINARY – RENAL

Advanced renal cell carcinoma progressing after tx with tyrosine kinase inhibitors .............................................. CTSU CALGB-90802
  Everolimus + Placebo vs Everolimus + Bevacizumab

GENITOURINARY – BLADDER

***Metastatic or unresectable transitional cell carcinoma of urinary tract.................................................................CALGB 90601
  Gemzar + Cisplatin + Placebo 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

GENITOURINARY – PROSTATE

Prostate cancer metastatic to bone (no prior bisphosphonate or radiopharmaceuticals) .......................................... CTSU CALGB-90202
IRB review pending -- Can be expedited upon request.
  Zoledronic Acid vs Placebo

Prevention of Erectile Dysfunction - stage T1b-T2b, M0 - Suspended due to problems with drug distribution .............. RTOG-0831
IRB review pending -- Can be expedited upon request.
  Tadalafil vs Placebo (start within 7 days after start of RT)

GYN

Previously untreated, epithelial ovarian, fallopian tube, primary peritoneal ............................................................... CTSU-GOG-0252
  Stage II, III, or IV with either optimal (≤ 1 cm residual disease) or suboptimal residual disease
Cycles 1 - 6:
  Paclitaxel IV days 1,8,15 + Carboplatin AUC 6 IV day 1 + Bevacizumab day 1 beginning cycle 2
  vs
  Paclitaxel IV days 1,8,15 + Carboplatin AUC 6 IP day 1 + Bevacizumab day 1 beginning cycle 2
  Vs
  Paclitaxel 135mg/m IV day 1 + Cisplatin 75mg/m² IP day 2 + Paclitaxel 60mg/m² IP day 8 + Bevacizumab day 1 beg cyc 2
Cycles 7 - 22 for all arms:
  Bevacizumab day 1
HEAD AND NECK

Locally-advanced resected head and neck cancer -- *Gross total resection of tumor; no prior chemo*.......................... RTOG 0920

\[T_{1N_{1,2}M_{0}} T_{2N_{0,2}M_{0}} T_{3M_{0}, T_{4a}} Microscopic T_{sa} \]

RT (2 Gy/day, in 30 fractions for total of 60 Gy)

vs

RTOG 0920

Cetuximab then RT (as above) + Cetuximab then Cetuximab

(250 mg/m²/week x 6) (250 mg/m²/week x 4)

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

Physician choice of chemotherapy regimens

Cisplatin doublet vs Cisplatin-doublet + Bevacizumab

LEUKEMIA

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

***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

Unresectable stage III or IV melanoma; ≤ 1 prior systemic therapeutic regimen ................................................................. ECOG E1608

Each enrolling investigator is required to review the slide deck entitled: E1608 Ipilimumab Immune Related Adverse Events: Summary and Recommended Management and complete the associated quiz prior to their first patient enrollment.

Cycles 1-4: GM-CSF (d1-14) + Ipilimumab (d1) then Cycles ≥ 5: GM-CSF (d1-14) + Ipilimumab (d1 every 4th cycle)

vs

Cycles 1-4: Ipilimumab (d1) then Cycles ≥ 5: Ipilimumab (d1 every 4th cycle)

MDS

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

or

Arm B -- Lenalidomide + epoetin alfa until relapse/progression
MULTIPLE MYELOMA

Newly diagnosed multiple myeloma – not candidates for high-dose therapy ............................................................. ECOG E1A06

Per IRB Approval: “any male or female that does not have to be started on birth control can be enrolled into the study…”

Melphalan + Prednisone + Thalidomide + Aspirin vs Melphalan + Prednisone + Lenalidomide + Aspirin

then

Thalidomide maintenance
then

Lenalidomide maintenance

THORACIC - SMALL CELL LUNG CANCER

Extensive Stage SCLC ................................................................. ECOG E1508

Cisplatin + Etoposide (4 cycles) then observation

vs

Cisplatin + Etoposide + GDC-0449 (4 cycles) then GDC-0449

vs

Cisplatin + Etoposide + IMC-A12 (4 cycles) then IMC-A12

THORACIC - NON-SMALL CELL LUNG CANCER

Stage 1 NSCLC, mass ≥ 2.0cm and ≤ 6.0cm in diameter on CT – patient must consent prior to surgery............ CTSU CALGB-30506

Obervation

vs

Physician choice: Maximum 4 cycles of cisplatin + (vinorelbine, docetaxel, gemcitabine, or premetrexed)

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

Stage IIIB or IV or recurrence after prior curative resection or definitive RT and non-smoker (≤ 100 cigarettes in lifetime) ................................................................. ECOG E2508

Placebo daily + Paclitaxel + Carboplatin + Bevacizumab(if eligible) for 6 cycles then Placebo +/- Bevacizumab

vs

Erlotinib daily + Paclitaxel + Carboplatin + Bevacizumab(if eligible) for 6 cycles then Erlotinib +/- Bevacizumab

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

Physician choice of: cisplatin + (vinorelbine, docetaxel, gemcitabine, or premetrexed)

vs

Physician choice of the above therapies + Bevacizumab

Advanced non-squamous NSCLC Suspended................................................................................................................... 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)  (d1,8,15)

Maintenance tx following initial 4 cycles of chemo in stage IIIB/IV NSCLC................................................................. CTSU CALGB-30607

Sunitinib vs Placebo

***Denotes newly activated study

^^^Denotes listing updated due to amendments made to the trial

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