



Genitourinary Newsletter

NCIC Clinical Trials Group Newsletter Date: August 2010



Actively Accruing GU Trials

Trial (Activation Date)	NCIC CTG Accrual (% of overall)	Overall Accrual/ Sample Size	# Open NCIC CTG Centres	Top Performers!
PR.11 (June 15, 2007)	97 (69%)	141/2130	11	London = 33 Sherbrooke = 25 Sunnybrook = 13
PR.13/ MRC PR.10 (Sept. 27, 2007)	116 (19%)	624/4000 (RT = 117) (HD = 507)	12	PMH = 40 Winnipeg = 22 Vancouver = 13
PRC.2/ CALGB 90202 (Feb. 07, 2006)	36 (7%)	505/680	5	London = 21 CHUM Notre Dame = 7 Edmonton = 7
PRC.3/ CALGB 90203 (Oct. 15, 2007)	49 (20%)	239/750	6	Vancouver = 26 PMH = 13 London = 4
REC.2/ ECOG 2805 (Sept. 14, 2006)	141 (8%)	1865/1923	17	PMH = 22 Calgary = 18 Ottawa = 16

PR.11—A Phase III Study of Active Surveillance Therapy Against Radical Treatment in Patients Diagnosed with Favourable Risk Prostate Cancer (**START**)

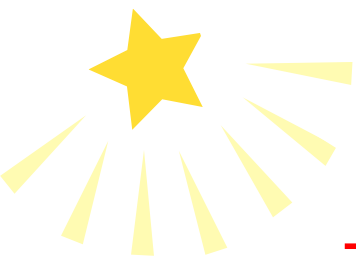
PR.13 (MRC PR.10)—RADICALS: Radiotherapy and Androgen Deprivation In Combination After Local Surgery

PRC.2 (CALGB 90202)—A Randomized, Double-Blind, Placebo-Controlled Phase III Study of Early Versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone

PRC.3 (CALGB 90203)— A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer

REC.2 (E2805)— ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavourable Renal Carcinoma





TRIAL SPOTLIGHT ON...PR.7



In consideration of the results of a recent interim analysis, the NCIC CTG PR.7 trial was determined by the Data Safety Monitoring Committee to have met its goal of demonstrating non-inferiority between Intermittent Androgen Deprivation (IAD) and Continuous Androgen Deprivation (CAD) with respect to overall survival. The trial was therefore closed as of May 18, 2010 and we are in the process of cleaning the data for final analysis, presentation and publication.



Please note there is an **embargo** on releasing any PR.7 results other than for PR.7 patient management purposes pending publication of these important findings.



As there is no requirement for further data to be submitted beyond May 18, 2010, we are encouraging centres to **submit all delinquent data and address outstanding queries as quickly as possible.**



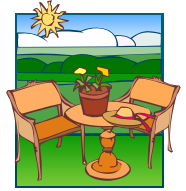
Thank you for the many years of patient treatment and follow-up that centres have dedicated to this trial. This trial would not have been such a success without the hard work of all your centre staff and with the end in sight we are asking for one final effort to finally reach our goal.

Congratulations!

A large blue ribbon graphic with a yellow outline, tied in a bow, positioned at the end of the 'Congratulations!' text.



TRIAL UPDATES



PR.3—Intergroup Phase III Randomized Trial Comparing Total Androgen Blockade Versus Total Androgen Blockade Plus Pelvic Irradiation in Clinical Adenocarcinoma of the Prostate

- ↳ On Monday June 7, 2010, the trial results were reported by Padraig R. Warde at the ASCO Annual Meeting in Chicago (Abstract CRA4504).
- ↳ The PR.3 data suggest that continuous androgen deprivation plus external beam radiation therapy “should be the standard treatment approach” for men with locally advanced prostate cancer, according to participants from the Genitourinary (Prostate) Cancer Oral Abstract Session at ASCO's Annual Meeting.
- ↳ The conclusion was based on observation of a significant improvement in both overall and disease-specific survival compared with androgen deprivation monotherapy.
- ↳ Thanks to everyone for their tremendous efforts towards helping to make this trial a success.
- ↳ The final analysis will be done when 421 events (deaths) have occurred. As of August 24, the total number of events was 406.
- ↳ Please be sure to continue to follow patients on a yearly basis.

PR.11—A Phase III Study of Active Surveillance Therapy Against Radical Treatment in Patients Diagnosed with Favourable Risk Prostate Cancer (START)

- ↳ On May 6, the PR.11 trial opened widely on the CTSU menu.
- ↳ Since that time, over 80 centres in the US have activated this study and have begun patient recruitment.
- ↳ The next 18 months are critical to the success of this trial and all sites are encouraged to utilize the patient educational video as a tool during the consent discussion.

REC.2— ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavourable Renal Carcinoma

- ↳ This trial is very close to achieving its accrual goal of 1923 patients.
- ↳ The lead group for this study issued a memo on August 2nd stating that this trial will be closed to accrual, effective September 1, 2010 at 5:00pm (EST).
- ↳ All patients must continue to be followed per protocol until the analysis.
- ↳ When available, publications of the trial results will be made available at the following link: https://scooby.ctg.queensu.ca/publications/displaying_publications.php

