Open clinical uro-oncology trials in Canada

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ADRENOCORTICAL MALIGNANCIES

CISPLATIN-BASED CHEMOTHERAPY AND/OR SURGERY IN TREATING YOUNG PATIENTS WITH ADRENOCORTICAL TUMOR

Trial ID:	NCT00304070, CDR0000467191, COG-ARAR0332
Trial design:	Stratified according to disease stage, with stage I and II patients undergoing surgery, stage III patients receiving induction chemotherapy (mitotane, cisplatin, etoposide and doxorubicin) followed by surgery if stable disease or partial response. Patients with stage IV disease undergo primary tumor resection (if feasible) with regional lymph node dissection and resection of the metastases. Patients then proceed to continuation chemotherapy. Continuation chemotherapy: cisplatin-based chemotherapy (as in induction chemotherapy) for 4-6 courses followed by mitotane alone for an additional 2 months. Patients with stage IV disease then proceed to additional surgery when feasible.
Patient population:	Young patients with newly diagnosed (within 3 weeks) stage I-IV adrenocortical malignancies, histologically proven, normal renal, hepatic and cardiac function.
Sample size & primary endpoint:	n = 235, response rate

BLADDER CANCER

A PHASE III STUDY OF IRESSA® IN COMBINATION WITH INTRAVESICAL BCG VERSUS INTRAVESICAL BCG ALONE IN HIGH RISK SUPERFICIAL TRANSITIONAL CELL CARCINOMA OF THE BLADDER

Trial ID: NCIC BL.11
Coordination: Cooperative group (NCIC CTG)
Trial design: A phase III study comparing intravesical BCG with and without gefitinib, an oral EGFR TK inhibitor.
Patient population: High risk Ta, Tis or T1 superficial bladder cancer with complete transurethral resection of all visible bladder lesions within 21 to 60 days prior to randomization, and without other evidence of metastasis.
Sample size & primary endpoint: n = 166, time to treatment failure

OPEN LABEL MULTICENTRE STUDY OF THE EFFICACY AND SAFETY OF MCC (MYCOBACTERIAL DNA) IN THE TREATMENT OF PATIENTS WITH NON-MUSCLE INVASIVE BLADDER CANCER AT HIGH RISK OF PROGRESSION AND WHO ARE REFRACTORY TO BCG

Coordination: Industry (Bioniche Life Sciences)
Trial Design: In the Induction phase, patients will receive 6 weekly intravesical instillations of 8 mg MCC. At month 3, patients will enter the Maintenance phase and will receive weekly MCC instillations for 3 weeks at months 3, 6, 12, 18 and 24.
Patient population: Patients with non-muscle invasive urothelial carcinoma at high risk of progression (CIS, T1G3) who have failed therapy with BCG.
Sample size & primary endpoint: n = 105; one year disease-free survival

RANDOMIZED PHASE III TRIAL COMPARING IMMEDIATE VERSUS DEFERRED CHEMOTHERAPY AFTER RADICAL CYSTECTOMY IN PATIENTS WITH PT3-PT4, AND/OR N+M0 TRANSITIONAL CELL CARCINOMA OF THE BLADDER

Trial ID: NCIC BL.8
Coordination: Intergroup (EORTC)
Trial design: A phase III study of immediate adjuvant chemotherapy with gemcitabine-cisplatin for 4 cycles versus chemotherapy at relapse after radical cystectomy.
Patient population: Transitional cell carcinoma of the bladder (pT2 incidental pT3 or pT4) and/or node positive (pN1-3) M0 following radical cystectomy and lymphadenectomy. Lymph node dissection of 15 or more lymph nodes is recommended. Patients must be able to start chemotherapy within 90 days after surgery.
Sample size & primary endpoint: n = 660, overall survival

A RANDOMIZED, PLACEBO-CONTROLLED PHASE II STUDY TO COMPARE THE EFFICACY AND SAFETY OF SU011248 PLUS BEST SUPPORTIVE CARE (BSC) VERSUS PLACEBO PLUS BSC IN PATIENTS WITH ADVANCED UROTHELIAL TRANSITIONAL CELL CARCINOMA WHO HAVE FAILED OR ARE INTOLERANT TO CISPLATIN CONTAINING CHEMOTHERAPY

Trial ID: SPRUCE
Coordination: Canadian Urologic Oncology Group
Trial design: A randomized phase II study comparing sunitinib to placebo.
Patient population: Recurrent or metastatic transitional cell carcinoma failed, intolerant of, or ineligible for first-line cisplatin-based combination chemotherapy.
Sample size & primary endpoint: n = 58, progression-free survival

PROSTATE ADENOCARCINOMA

LOCALIZED PROSTATE CANCER

Low Risk

A PHASE III STUDY OF ACTIVE SURVEILLANCE THERAPY AGAINST RADICAL TREATMENT IN PATIENTS DIAGNOSED WITH FAVORABLE RISK PROSTATE CANCER (START)

Trial ID: NCIC CTG PR11
Coordination: National Cancer Institute of Canada
Trial design: A phase III study comparing radical prostatectomy or radical radiotherapy at the time of initial diagnosis to active surveillance and selective intervention based on pre-specified biochemical, histological or clinical criteria.
Patient population: Suitable candidates for radical prostatectomy or radiotherapy. No previous treatment for prostate cancer for greater than 6 months. Favorable risk as defined by the following: clinical stage T1b, T1c, T2a or T2b, surgical Gleason score <= 6, PSA <= 10.0 ng/ml.
Sample size & primary endpoint: n = 2130, disease specific survival

A PHASE III RANDOMIZED STUDY OF HYPOFRACTIONATED 3D-CRT/IMRT VERSUS CONVENTIONALLY FRACTIONATED 3D-CRT/IMRT IN PATIENTS WITH FAVORABLE-RISK PROSTATE CANCER

Trial ID: RTOG 0415
Coordination: Cooperative group (Radiation Therapy Oncology Group)
Trial design: A randomized phase III non-inferiority trial assessing hypofractionated radiation of 70 Gy in 28 fractions to the prostate versus standard fractionation of 73.8 Gy in 41 fractions.
Patient population: Low-risk localized prostate cancer.
Sample size & primary endpoint: n = 1067, disease-free survival

Intermediate Risk

A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT/IMRT VERSUS STANDARD DOSE 3D-CRT/IMRT IN PATIENTS TREATED FOR LOCALIZED PROSTATE CANCER

Trial ID: RTOG 0126
Coordination: Cooperative group (RTOG)
Trial design: A randomized phase III superiority clinical trial assessing dose-escalated radiation of 79.2 Gy in 44 fractions versus standard fractionation of 70.2 in 39 fractions.
Patient population: Intermediate-risk prostate cancer.
Sample size & primary endpoint: n = 1520, overall survival

PROSTATE FRACTIONATED IRRADIATION TRIAL (PROFIT)

Coordination: Cooperative group (Ontario Clinical Oncology Group)
Trial design: A phase III study assessing the relative efficacy of dose-escalated radiation therapy (78 Gy in 39 fractions) versus a hypofractionated course of radiation (6000 Gy in 20 fractions).
Patient population: Intermediate-risk prostate cancer.
Sample size & primary endpoint: n = 1204, biochemical (PSA) failure

High Risk

A PHASE III STUDY OF NEOADJUVANT DOCETAXEL AND ANDROGEN SUPPRESSION PLUS RADIATION THERAPY VERSUS ANDROGEN SUPPRESSION ALONE PLUS RADIATION THERAPY FOR HIGH-RISK LOCALIZED ADENOCARCINOMA OF THE PROSTATE (DART)

Trial ID: NCIC PR12
Coordination: National Cancer Institute of Canada
Trial design: A randomized phase III relative efficacy assessment of 3 years of androgen suppression combined with radical external beam radiation therapy (70 Gy-73 Gy) plus or minus neoadjuvant docetaxel chemotherapy (four cycles, 75 mg/m^2 q21 days).
Patient population: High-risk prostate cancer.
Sample size & primary endpoint: n = 530, disease-free survival

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

Trial ID: NCI CDR0000526353
Coordination: Intergroup (National Cancer Institute)
Trial design: A phase III comparison of neoadjuvant chemohormonal therapy with goserelin or leuprolide for 18-24 weeks with docetaxel IV every 3 weeks for up to six courses followed by radical prostatectomy with staging pelvic lymphadenectomy versus radical prostatectomy with staging lymphadenectomy alone.
Patient population: High-risk prostate cancer.
Sample size & primary endpoint: n = 750, 3 year biochemical progression-free survival

RANDOMIZED PHASE III TRIAL OF 3D CONFORMAL RADIOTHERAPY VERSUS HELICAL TOMOTHERAPY IMRT IN HIGH-RISK PROSTATE CANCER

Coordination: Investigator led (Ottawa Regional Cancer Program)
Trial design: A phase III randomized relative efficacy comparison of three-dimensional conformal radiation therapy versus helical tomotherapy with 78 Gy in 39 fractions and 3 years of LHRH therapy.
Patient population: High-risk prostate cancer.
Sample size & primary endpoint: n = 72, late rectal toxicity

A PHASE III PROTOCOL OF ANDROGEN SUPPRESSION (AS) AND 3DCRT/IMRT VS AS AND 3DCRT/IMRT FOLLOWED BY CHEMOTHERAPY WITH DOCETAXEL AND PREDNISONE FOR LOCALIZED, HIGH-RISK PROSTATE CANCER

Trial ID: RTOG 0521
Study type: Cooperative group
Trial design: A randomized phase III relative efficacy assessment of 2 years of androgen suppression combined with radical external beam radiation therapy (72 Gy-75.6 Gy) with or without adjuvant docetaxel chemotherapy (six cycles, 75 mg/m^2 q21 days).
Patient population: High-risk prostate cancer.
Sample size & primary endpoint: n = 600, overall survival

PHASE III, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFICACY OF ZOMETA® FOR THE PREVENTION OF OSTEOPOROSIS AND ASSOCIATED FRACTURES IN PATIENTS RECEIVING RADIATION THERAPY AND LONG TERM LHRH AGONISTS FOR HIGH-GRADE AND/OR LOCALLY ADVANCED PROSTATE CANCER

Trial ID: RTOG 0518
Coordination: Intergroup (RTOG)
Trial design: This randomized phase III trial is studying zoledronate versus placebo in the prevention of osteoporosis and bone fractures in patients with locally advanced nonmetastatic prostate cancer undergoing radiation therapy and hormone therapy.
Patient population: Prostate cancer diagnosed within the past 6 months, clinical stage T3 OR Gleason score ≥ 8 OR PSA ≥ 30 ng/mL OR Gleason score ≥ 7 and PSA ≥ 15 ng/mL, baseline T score > -2.5 in both the L spine and the total hip by dual x-ray absorptiometry scan, and scheduled to receive a LHRH agonist for ≥ 1 year.
Sample size & primary endpoint: n = 1272, freedom from any bone fracture

BIOCHEMICALLY RELAPSED PROSTATE CANCER

A PHASE II TRIAL OF SHORT-TERM ANDROGEN DEPRIVATION WITH PELVIC LYMPH NODE OR PROSTATE BED ONLY RADIOTHERAPY (SPORT) IN PROSTATE CANCER PATIENTS WITH A RISING PSA AFTER RADICAL PROSTATECTOMY

Study type: Cooperative group RTOG 0534
Trial design: Phase II comparing radiotherapy alone to radiotherapy with short-term androgen deprivation.
Patient population: Males who have undergone radical prostatectomy, followed by PSA rise to > 0.2 ng/ml.
Sample size & primary endpoint: n = 1764, 5-year freedom from progression

A RANDOMIZED COMPARISON OF IMMEDIATE VERSUS DEFERRED ANDROGEN DEPRIVATION THERAPY USING GOSERELIN FOR RECURRENT PROSTATE CANCER AFTER RADICAL RADIOTHERAPY (ELAAT)

Study type: Cooperative group (Ontario Clinical Oncology Group)
Trial design: A phase III trial comparing immediate to deferred androgen deprivation therapy.
Patient population: Patients who have undergone prior radical radiation for prostate cancer and are now experiencing a biochemical recurrence.
Sample size & primary endpoint: n = 1100, time to androgen independent disease

METASTATIC PROSTATE CANCER

PHASE III STUDY OF INTERMITTENT ANDROGEN DEPRIVATION IN PATIENTS WITH STAGE D2 PROSTATE CANCER

Trial ID: NCICPR8, SWOG-9346

Coordination: Intergroup (SWOG)

Trial design/treatment: Randomized, multicenter study. Induction therapy: Patients receive combined androgen-deprivation (CAD) therapy comprising goserelin subcutaneously once a month and oral bicalutamide once daily for 8 courses (7 months). Patients are then randomized to 1 of 2 consolidation regimens. Arm I continuous CAD until disease progression. Arm II (intermittent CAD): Patients undergo observation only in the absence of rising prostate-specific antigen (PSA) or clinical symptoms of progressive disease. Patients with rising PSA or progressive disease begin CAD as in induction therapy.

Patient population: Histologically or cytologically confirmed adenocarcinoma of the prostate, clinical stage D2 as evidenced by soft tissue and/or bony metastases.

Sample size & primary endpoint: n = 1512, quality of life

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

Trial ID: NCIC PRC2

Coordination: Intergroup (Cancer And Leukemia Group B)

Trial design: A phase III study comparing treatment with zoledronic acid at the time of initiation of androgen deprivation therapy for metastatic prostate cancer to treatment at time of progression to hormone-refractory disease.

Patient population: Metastatic prostate cancer with at least one bone metastasis by radiographic imaging receiving androgen deprivation therapy.

Sample size & primary endpoint: n = 680, time to first skeletal related event

HORMONE REFRACTORY PROSTATE CANCER

A PHASE III RANDOMIZED DOUBLE-BLIND STUDY TO ASSESS THE EFFICACY AND SAFETY OF 10 MG ZD4054 VERSUS PLACEBO IN PATIENTS WITH HORMONE-RESISTANT PROSTATE CANCER AND BONE METASTASES WHO ARE PAIN-FREE OR MILDLY SYMPTOMATIC

Trial ID: D4320C00014
Coordination: Industry: AstraZeneca
Trial design: Placebo controlled phase III trial
Patient population: HRPC with mildly/asymptomatic bone metastases, chemotherapy-naïve.
Sample size & primary endpoint: unavailable

A PHASE II STUDY OF BAY 43-9006 IN COMBINATION WITH BICALUTAMIDE IN PATIENTS WITH CHEMO-NAÏVE HORMONE REFRACTORY PROSTATE CANCER

Trial ID: OZM-001
Coordination: Ozmosis Research Inc.
Trial design: A 2-stage phase II clinical trial
Patient population: Progressive prostate cancer despite androgen ablation, low-bulk asymptomatic metastatic or biochemical recurrent disease without curative therapy, and no prior palliative chemotherapy.
Sample size & primary endpoint: n = 37, PSA response rate

A MULTICENTRE, RANDOMIZED, DOUBLE-BLIND STUDY COMPARING THE EFFICACY AND SAFETY OF AFLIBERCEPT VERSUS PLACEBO EVERY 3 WEEKS IN PATIENTS TREATED WITH DOCETAXEL/PREDNISONE FOR METASTATIC ANDROGEN INDEPENDENT PROSTATE CANCER

Trial ID: VENICE/ EFC6546
Coordination: Industry (sanofi-aventis)
Trial design: A phase III study comparing the addition of aflibercept to standard docetaxel/prednisone.
Patient population: Metastatic hormone-refractory prostate cancer and no prior palliative chemotherapy.
Sample size & primary endpoint: n = 1200, overall survival

A RANDOMIZED, OPEN-LABEL MULTICENTRE STUDY OF XRP-6258 AT 25 MG/M^2 IN COMBINATION WITH PREDNISONE EVERY 3 WEEKS COMPARED TO MITOXANTRONE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF HORMONE-REFRACTORY METASTATIC PROSTATE CANCER PREVIOUSLY TREATED WITH A TAXOTERE-CONTAINING REGIMEN

Coordination: sanofi-aventis
Trial design: Randomized phase III
Patient population: Hormone-refractory prostate cancer previously treated with docetaxel.
Sample size & primary endpoint: n = 720, overall survival

RENAL CELL CANCER

A RANDOMIZED, DOUBLE-BLIND PHASE III TRIAL OF ADJUVANT SUNITINIB VERSUS SORAFENIB VERSUS PLACEBO IN PATIENTS WITH RESECTED RENAL CELL CARCINOMA (ASSURE)

Trial ID: NCIC REC.2
Coordination: Intergroup (ECOG)
Trial design: A phase III surgical adjuvant study assessing the effectiveness of sunitinib or sorafenib compared to placebo.
Patient population: Resected renal cell carcinoma, T1b grade 3-4 or higher and/or N+.
Sample size & primary endpoint: n = 1332, overall survival

A PHASE II SINGLE ARM, PROSPECTIVE STUDY OF NEOADJUVANT SUTENT® FOR PATIENTS WITH RENAL CELL CARCINOMA

Trial ID: NCT00480935, 07-0017-C
Coordination: University Health Network, Toronto, ON and Industry (Pfizer)
Trial design/treatment: Sutent will be given at 50 mg once daily for 4 consecutive weeks followed by a 2 week rest period (6 week cycle). Patients will then continue on Sutent for an additional 4 weeks. The nephrectomy will then take place following a washout period of 48 hours to 2 weeks depending on safety.
Patient population: Histologically confirmed renal cell carcinoma with a component of clear cell histology, which has been assessed with biopsy at screening with locally confined tumor no more than 7 cm.
Sample size & primary endpoint: n = 30, objective response rate

PRE-OPERATIVE ADMINISTRATION OF SORAFENIB IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA UNDERGOING CYTOREDUCTIVE NEPHRECTOMY

Trial ID: NCT00480389, 06-0655-C
Coordination: University Health Network, Toronto, ON and Industry (Bayer)
Trial design/treatment: Single centre, one arm study of Sorafenib 400 mg twice daily given for 12 weeks preoperatively in patients with advanced metastatic kidney cancer scheduled for cytoreductive surgery.
Patient population: Biopsy proven RCC with a component of clear cell type histology, at least one site of measurable disease, medical candidate for cytoreductive nephrectomy, no vena caval thrombus, no brain metastases.
Sample size & primary endpoint: n = 30, correlation of pathological response with time to progression

SORAFENIB IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA RESISTENT TO SUTENT®

Trial ID: OCT1163, OZM SU Resist, OZM-002
Coordination: Toronto Sunnybrook Regional Cancer Centre
Trial design/treatment: Phase I, sorafenib treatment details unavailable.
Patient population: Patients with measurable histologically confirmed metastatic clear cell RCC de novo resistant to Sutent therapy or progressing after initial response or stability of disease. Patients previously treated with Sorafenib or Avastin are not eligible.
Sample size & primary endpoint: not available

TESTICULAR CANCER

PHASE II STUDY OF SUNITINIB IN MALE PATIENTS WITH RELAPSED OR CISPLATIN-REFRACTORY GERM CELL CANCER

Trial ID:	CUOG-TE 05, NCT00371553
Coordination:	Canadian Urologic Oncology Group, National Cancer Institute of Canada, German Testicular Cancer Study Group (GTSCG)
Trial design/treatment:	Phase II, single arm. Sunitinib will be given at 50 mg once daily for 4 consecutive weeks followed by a 2-week rest period to comprise a complete cycle of 6 weeks.
Patient population:	Histologically proven seminomatous or non-seminomatous germ cell cancer, patients with relapse within 8 weeks after at least two different cisplatin- based regimens or patients with disease progression or relapse after salvage high-dose chemotherapy or patients with disease progression during cisplatin-based and measurable disease.
Primary endpoint:	response rate