Open clinical uro-oncology trials in Canada

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LOCALIZED PROSTATE CANCER

Post-Radical Prostatectomy

A MULTICENTER, OPEN-LABEL, RANDOMIZED, PHASE III TRIAL COMPARING IMMEDIATE ADJUVANT HORMONAL THERAPY (ELIGARD®- LEUPROLIDE ACETATE) IN COMBINATION WITH TAXOTERE® (DOCETAXEL) ADMINISTERED EVERY 3 WEEKS VERSUS HORMONAL THERAPY ALONE VERSUS DEFERRED THERAPY FOLLOWED BY THE SAME THERAPEUTIC OPTIONS IN PATIENTS WITH PROSTATE CANCER AT HIGH RISK OF RELAPSE AFTER RADICAL PROSTATECTOMY (ATLAS)

Coordination: Industry (sanofi-aventis)
Trial design: A phase III adjuvant study comparing imediate treatment with LHRH agonist with or without docetaxel to deferred treatment with LHRH agonist with or without docetaxel.
Patient population: High-risk post radical prostatectomy defined as a predicted probability of 5-year freedom from progression ≤ 60% determined by Kattan postoperative nomogram.
Sample size & endpoint: n = 1696, progression-free survival as primary endpoint

RADIOTHERAPY AND ANDROGEN DEPRIVATION IN COMBINATION AFTER LOCAL SURGERY (RADICALS)

Trial ID: NCIC PR13
Coordination: Intergroup (MRC)
Trial design: A phase III study investigating immediate or deferred radiation with or without androgen deprivation therapy post radical prostatectomy.
Patient population: All men post radical prostatectomy.
Sample size & endpoint: n = 4000, disease-specific survival as primary endpoint

Low Risk

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

Trial ID: NCIC CTG PR11
Coordination: Intergroup (NCIC CTG)
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 & endpoint: n = 2130, disease specific survival as primary endpoint

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 (RTOG)
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 & endpoint: n = 1067, disease-free survival as primary endpoint

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 & endpoint: n = 1520, overall survival as primary endpoint

PROSTATE FRACTIONATED IRRADIATION TRIAL (PROFIT)

Coordination: Cooperative group (Ontario Clinical Oncology Group)
Study type: Cooperative group (OCOG)
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 & endpoint: n = 1204, biochemical (PSA) failure as primary endpoint

High Risk

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

Coordination: Investigator led (Dr. S. Malone, 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 & endpoint: n = 72, late rectal toxicity as primary endpoint

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 & endpoint: n = 600, overall survival as primary endpoint

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: Cooperative group (NCIC CTG)
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 & endpoint: n = 530, disease-free survival as primary endpoint

BIOCHEMICALLY RELAPSED PROSTATE CANCER

NEOADJUVANT DOCETAXEL FOLLOWED BY SALVAGE RT PLUS 2-YEAR HORMONE THERAPY FOR RESIDUAL OR RECURRENT PROSTATE ADENOCARCINOMA FOLLOWING RADICAL PROSTATECTOMY

Coordination: Industry (sanofi-aventis)
Trial design: A phase II study of neoadjuvant chemohormonal therapy including weekly docetaxel prior to salvage radiotherapy and adjuvant LHRH agoinst therapy.
Patient population: Prior radical prostatectomy and PSA failure plus one of: PSA > 2 ng/ml, Gleason score > 8 and PSA > 1, pT3b and PSA > 1, or pPT3a with positive resection margin and PSA > 1 with PSA failure < 12 months.
Sample size & endpoint: n = 48, feasibility and toxicity as primary endpoints

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 recurrence.
Sample size & endpoint: n = 1100, time to androgen independent disease as primary endpoint

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 to see how well it works compared to a placebo in preventing 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 & endpoint: n = 1272, freedom from any bone fracture as primary endpoint

METASTATIC PROSTATE CANCER

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 (CALGB)
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 & endpoint: n = 680, time to first skeletal related event as primary endpoint

HORMONAL REFRACTORY PROSTATE CANCER

DN-101 IN COMBINATION WITH DOCETAXEL IN ANDROGEN-INDEPENDENT PROSTATE CANCER

Trial ID: ASCENT 2
Coordination: Industry (Novacea)
Trial design: A phase III study of treatment with docetaxel with and without DN-101, an oral high potency vitamin D analogue.
Patient population: Hormone refractory prostate cancer with evidence of metastases.
Sample size & endpoint: n = 900, overall survival as primary endpoint

A PILOT STUDY EVALUATING THE SAFETY AND FEASIBILITY OF OGX-011 IN COMBINATION WITH SECOND LINE CHEMOTHERAPY IN PATIENTS WITH HORMONE REFRACTORY PROSTATE CANCER

Coordination: Industry (Oncogenex)
Trial design: A phase II study of docetaxel plus OGX-011, an intravenously administered antisense oligonucleotide to the antiapoptotic protein clusterin.
Patient population: Hormone refractory prostate cancer previously treated with docetaxel.
Sample size & endpoint: n = 65, evaluable, toxicity as primary endpoint

PATUPILONE (EPO906) AND PREDNISONE IN METASTATIC HORMONE REFRACTORY PROSTATE CANCER

Coordination: BC Cancer Agency
Trial design: A phase II study of patupilone 8 mg/m^2 IV q3weeks with oral prednisone
Patient population: Hormone refractory prostate cancer previously treated with docetaxel.
Sample size & endpoint: n = 73, PSA response rate as primary endpoint

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 & endpoint: n = 1332, overall survival as primary endpoint

A PHASE II STUDY OF AZD2171 IN PROGRESSIVE UNRESECTABLE, RECURRENT OR METASTATIC RENAL CELL CARCINOMA

Trial ID: PHL-039
Coordination: Cooperative group (Princess Margaret Hospital Phase II Consortium)
Trial design: A phase II study of AZD2171, an oral tyrosine kinase inhibitor targeting vascular endothelial growth factor.
Patient population: Previously untreated incurable renal carcinoma with measurable disease.
Sample size & endpoint: n = 37, clinical benefit rate (objective response + stable disease > 4 months) as primary endpoint

EVEROLIMUS IN PATIENTS WHO HAVE PROGRESSED ON VEGFR TK INHIBITORS

Trial ID: RAD001C2240
Coordination: Industry (Novartis)
Trial design: A phase III study with blinded randomization in a 2:1 fashion to either everolimus (RAD001), an oral inhibitor of mammalian target of rapamycin (mTOR), or placebo.
Patient population: Recurrent or metastatic renal cell carcinoma with documented progression of disease on an inhibitor of vascular endothelial growth factor (e.g. sunitinib or sorafenib).
Sample size & endpoint: n = 362, progression-free survival as primary endpoint

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 & endpoint: n = 166, time to treatment failure as primary endpoint

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 & endpoint: n = 660, overall survival as primary endpoint

A MULTI–CENTRE, RANDOMIZED, DOUBLE-BLIND, PHASE 2/3 STUDY IN FIRST LINE TREATMENT OF ADVANCED TRANSITIONAL CELL CARCINOMA (TCC) OF THE UROTHELIUM COMPARING VINFLUNINE/GEMCITABINE TO PLACEBO/GEMCITABINE IN PATIENTS WHO ARE INELIGIBLE TO RECEIVE CISPLATIN BASED THERAPY (VINCENT).

Coordination: Industry (Bristol-Myers-Squibb)
Trial design: A phase III study comparing gemcitabine plus vinflunine to gemcitabine monotherapy in patients unsuitable for cisplatin-based combination chemotherapy.
Patient population: Incurable locally advanced, recurrent, or metastatic transitional cell carcinoma unsuitable for conventional cisplatin-based chemotherapy due to poor renal or cardiac function.
Sample size & endpoint: n = 450, overall survival as primary endpoint