



**N. Ireland Cancer Clinical Trials Unit/  
N. Ireland Cancer Trials Network  
Trials Open to Recruitment – August 2010**

**Breast Cancer**

**IBIS II DCIS** An international multi-centre study of tamoxifen vs anastrozole in postmenopausal women with ductal carcinoma in situ (DCIS)

**IBIS II Prevention** – An international multi-centre study of anastrozole vs placebo in postmenopausal women at increased risk of breast cancer

**IBIS II Bone Sub** - International Breast cancer Intervention Study (IBIS) of anastrozole vs placebo in postmenopausal women at increased risk of breast cancer – Bone Sub study

**Supremo** A Phase III Randomised Trial to Assess the role of adjuvant chest wall irradiation in intermediate risk breast cancer after mastectomy (*also available in the Ulster Hospital*)

**IMPORT LOW** Intensity Modulated and Partial Organ Radiotherapy Following Breast Conservation Surgery For Early Breast Cancer

**OHERA** An observational study of cardiac events in patients with HER2 positive early breast cancer treated with Herceptin

**TNT** A randomised phase III comparative trial of carboplatin versus docetaxel for patients with ER- PR- HER2- advanced breast cancer (*also available in Altnagelvin*)

**POETIC** Trial of Perioperative Endocrine Therapy - Individualising Care (*also available in Craigavon and Ulster Hospital*)

**RETROSPECTIVE TNT** A translational research study investigating different gene expression profiles in triple receptor negative breast cancer

**L00070 Vinflunine** A phase III trial of vinflunine + capecitabine versus capecitabine alone in patients with advanced breast cancer previously treated with or resistant to an anthracycline and who are taxane resistant

## **Prostate Cancer**

**Stampede** Systemic Therapy in Advancing or Metastatic Prostate cancer - Evaluation of Drug Efficacy

**BC1-06** A double-blind, randomised, multiple dose, phase III, multi-centre study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases

**CHHIP** Conventional Or Hypofractional High Dose Intensity Modulated Radiotherapy For Prostate Cancer

**UKGPC** UK Genetics Prostate Cancer Study (*also available in Altnagelvin, Craigavon and Ulster Hospital*)

**Prostate Nutrition Study** A randomised controlled trial to evaluate the efficacy of a 6 month dietary and physical activity intervention for prostate cancer patients receiving androgen deprivation therapy

**Dex-IL8** A Study Examining The Association Of Serum Interleukin-8 (IL-8) With Response To Dexamethasone In Metastatic Hormone-Refractory Prostate Cancer (HRPC)

**Radicals** Radiotherapy and Androgen Deprivation in Combination after Local Surgery. A Randomised Controlled Trial in Prostate Cancer

**Triptocare** Prostate Cancer Antigen3 (PCA3) And TMPRSS2ERG (T2ERG) Score Changes During Initiation Of Androgen Deprivation Therapy (ADT) With Triptorelin (22.5mg) In Patients With Advanced Prostate Cancer (Pca): A Phase III, Single Arm Multi-Centre Study (*available in Ulster Hospital only*)

## **Renal Cancer**

**SORCE** A Phase III Randomised, Double-Blind Study Comparing Sorafenib with Placebo in Patients with Resected Primary Renal Cell Carcinoma at High or Intermediate Risk of Relapse

## **Testicular Cancer**

**UK TGCT Genetics Study** Identification of testicular germ cell tumour susceptibility genes – the UK genetics of testicular cancer study

## **Head and Neck Cancer**

**Determin** Determination of Quality of Life Instrument most preferred by Head and Neck Cancer patients

## **Bowel Cancer**

**QUASAR 2** A Multi-Centre, International Study of Capecitabine  $\pm$  Bevacizumab as Adjuvant Treatment of Colorectal Cancer (*also available in Altnagelvin*)

**NSCCG** National Study Of Colorectal Cancer Genetics (*also available in Altnagelvin, Antrim, Craigavon and Ulster Hospital*)

**SCOT** Short Course Oncology Therapy

## **Oesophageal and Stomach Cancers**

**TELOVAC** A Prospective, Phase II, Controlled, Multi-Centre, Randomised Clinical Trial Comparing Gemcitabine & Capecitabine Therapy With Concurrent, Sequential Chemo-Immunotherapy Using A Telomerase Vaccine in Locally Advanced & Metastatic Pancreatic Cancer

**STO3** A Randomised Phase II/III Trial of Peri-Operative Chemotherapy with or without Bevacizumab in Operable Adenocarcinoma of the Stomach and Gastro- oesophageal Junction

**SOCS** Stomach and Oesophageal Cancer Study (*also available in Altnagelvin Hospital*)

### **Early Phase Trials**

**VECarboX** A Dose Finding Study of Bortezomib in Addition to Epirubicin, Carboplatin and Capecitabine (ECarboX) in Advanced Gastric and Gastro-Oesophageal Junction Adenocarcinoma

**TP300** A Phase IIa, Open-Label, Multicentre Study of TP300 as a Single Agent First Line Therapy in Patients with Advanced Gastric or Gastro-Oesophageal Junction Adenocarcinoma

## **Lung Cancer**

**MAGRIT** A double blind, randomised, placebo-controlled Phase III Study to assess the efficacy of RecMAGE-A3 plus ASIS Antigen Specific Cancer Immunotherapeutic as adjuvant therapy in patients with respectable MAGE-A3-positive non-small cell lung cancer

**CONVERT** Concurrent Once-Daily Versus Twice-Daily Radiotherapy: A 2-arm randomized, Controlled Trial of Concurrent Chemo-radiotherapy Comparing Twice-daily and Once-daily Radiotherapy Schedules in Patients with Limited Stage Small Cell Lung Cancer (SCLC) and Good Performance Status

**QUARTZ** A Phase III Multi-Centre Randomised Controlled Trial To Assess Whether Optimal Supportive Care Alone (including Dexamethasone) Is As Effective As Optimal Supportive Care (including Dexamethasone) Plus Whole Brain Radiotherapy In The Treatment Of Patients With Inoperable Brain Metastases From Non-Small Cell Lung Cancer

**LUNG SEARCH** A randomised controlled trial of surveillance for the early detection of lung cancer in a high-risk group

## **Ovarian Cancer**

**CHORUS** Chemotherapy or Upfront Surgery. A randomised feasibility trial to determine the impact of timing of surgery and chemotherapy in newly diagnosed patients with advanced epithelial ovarian, primary peritoneal or fallopian tube cancer

**MORPHOTEK** A Randomised, Double-Blind, Placebo-Controlled, Phase III Study to Assess the Efficacy and Safety of Weekly Farletuxumab (MORAb-003) in Combination with Carboplatin and Taxane in Subjects with Platinum-Sensitive Ovarian Cancer in First Relapse

## **Lymphoma**

**PET/RAPID** A Randomised Phase III Trial To Determine The Role Of Fdg – Pet Imaging In Clinical Stages Ia/IIa Hodgkin's Disease (*also available Ulster Hospital*)

**R-GCVP** A Phase II Multicentre Trial of Gemcitabine, CVP and Rituximab (R-GCVP) for the Treatment of Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma, Considered Unsuited for R-CHOP chemotherapy

## **Leukaemia**

**AML 16** A Programme of Treatment Development for Older Patients with AML or High Risk MDS (*also available Altnagelvin Hospital*)

**FCLL** Genetic Study of Chronic Lymphocytic Leukaemia (*also available in Altnagelvin Antrim and Craigavon*)

**Nilotinib** A Phase II Multi-Centre, Open-label, Study of Nilotinib at a Dose of 300mg Twice Daily in Adult Patients with Newly Diagnosed Philadelphia Chromosome Positive (PH+) Chronic Myelogenous Leukaemia in Chronic Phase (CML-CP)

**OMB110911/COMPLEMENT** A Phase III, Open label, Randomized, Multicentre, Trial of Ofatumumab added to Chlorambucil vs. Chlorambucil Monotherapy in previously untreated patients with Chronic Lymphocytic Leukaemia

**SPIRIT 2:** ST1571 Prospective International Randomised Trial 2 - A Phase III, Prospective Randomised Comparison Of Imatinib (ST1571, Glivec/Gleevec) 400mg daily versus Dasatinib (Sprycel) 100mg daily In Patients With Newly-Diagnosed Chronic Phase Chronic Myeloid Leukaemia

## **Multiple Myeloma**

**Myeloma X** A phase III study to determine the role of a second autologous stem cell transplant as consolidation therapy in patients with relapsed multiple myeloma following prior high-dose chemotherapy and autologous stem cell rescue

## **Other Haematological**

**PT1** An MRC Randomised Trial To Compare Aspirin versus Hydroxyurea / Aspirin in 'Intermediate Risk' Primary Thrombocythaemia and Hydroxyurea / Aspirin versus Anagrelide / Aspirin in 'High Risk' Primary Thrombocythaemia (*also available in Altnagelvin, Antrim, Craigavon and Ulster Hospital*)

## **Studies not specific to a particular type of cancer**

### **Palliative care**

**EPAT** Does The Institutionalisation of Pain Assessment Using The EPAT Package Reduce Pain In Cancer Unit In-Patients More Than Usual Care. A Cluster Randomised Trial?

### **Complementary Therapy (Lung and colorectal cancer)**

An Exploration of how Older People with Cancer View Registered Complementary Therapy Services in N. Ireland (*also available in Marie Curie Hospice, Belfast*)

### **Early Phase Trial**

**A4991014** A Parallel Arms Phase 1 Safety, Pharmacokinetic And Pharmacodynamic Study Of The Intravenous Poly(ADP-RIBOSE) Polymerase (PARP) Inhibitor PF-01367338 (AG-014699) In Combination with Several Chemotherapeutic Regimens In Adult Patients With Advanced Solid Tumours

### **Translational Research**

**HER Shedding** A pilot study investigating the predictive role of chemotherapy-induced changes in serum Human Epidermal Receptor (HER) ligand levels in patients with metastatic colorectal cancer/non small cell lung cancer

## **Children's Cancers (Royal Belfast Hospital for Sick Children)**

**EURO EWING 99 (ET 2000 03)** European Ewing Tumour Working Initiatives of National Groups: Ewing Tumours Studies 1999

**Low Grade Glioma 2004 (CNS 2004 03)** Cooperative Multicentre Study for Children and Adolescents with Low Grade Glioma

**Relapsed Ependymoma (CNS 2001 04)** Phase II study of intravenous Etoposide in Patients with Relapsed Ependymoma

**High Risk Neuroblastoma (NB 2002 06)** High Risk Neuroblastoma

**Non Metastatic Rhabdomyosarcoma (STS 2006 04)** Non metastatic Rhabdomyosarcoma

**SIOP Wilms (WT 2002 01)** SIOP Nephroblastoma Clinical Trial

**ALL 2003** Medical Research Council Working Party on Leukaemia in Children UK National Acute Lymphoblastic Leukaemia (ALL) Trial UKALL 2003

**Relapsed ALL (ALLR3)** Relapsed ALL