

NCRI Radiotherapy Clinical Studies Group

The work of the Radiotherapy Clinical Studies Group continues to focus on trial development, translational research and radiotherapy quality assurance and these three elements form the basis of our strategy for the group over the next three years. With this in mind two subgroups have now been established, the first to develop proposals focussing on the many new and emerging technologies in radiotherapy and the second to develop translational programmes based on clinical trials involving radiotherapy.

The importance of radiotherapy quality assurance (QA) in clinical trials has been promoted by the group since its inception and has now become a major component of our work. A broad portfolio of trials are now managed by the NCRI Radiotherapy Quality Assurance co-ordinated by a senior quality assurance physicist with a team of physicists and radiographers based at Mount Vernon and the Royal Marsden Hospitals. Increasingly the group is approached to advise on the design of the radiotherapy component of new trials and the appropriate QA; ready access has been ensured through the web site, accessible via a link from the NCRN home page through the Radiotherapy CSG. Radiotherapy QA has now been recognised as an essential supporting activity for clinical trials by the Department of Health and central funding of these activities to ensure a core infrastructure has been secured.

Membership

We have been fortunate in having a portfolio co-ordinator, Mark Sydenham join the group to support its activities and are pleased to welcome new members to the group: Dr V Khoo and Dr C Nutting. We are grateful to the following members for their invaluable input to the group who are now leaving: Dr J Logue, Dr D Morgan and Professor A Price.

Annual meeting

Our fourth annual open meeting was held in December 2005 with the theme of late radiation morbidity. As the number of long-term cancer survivors increases, the late complications of treatment are being increasingly recognized as important. The meeting provided an important arena for discussing the increasing potential for randomized trials investigating the amelioration of radiation-induced toxicity. New trial initiatives were discussed, several of which have been developed into funded protocols.

Portfolio

The Group continues to work with CTAAC in reviewing proposals for funding having a radiotherapy component and has developed cross representation with ACORRN (Academic Clinical Oncology and Radiobiology Research Network). Trials with a significant radiotherapy component are given below.

Radiotherapy Group Portfolio

Trials in the NCRN portfolio with a significant radiotherapy component

Acronym	Title	PI(s)	Status
ACT II	A Second UK Phase III Anal Cancer Trial: A Trial of Chemoradiation and Maintenance Therapy for Patients with Anal Cancer	Professor Roger James	Open
Adjuvant Stomach Chemotherapy	Post operative chemo-radiotherapy after surgical resection of gastric and oesophageal cancer. A multi-centre phase I-II study of a fixed radiotherapy regimen	Dr Mark Saunders	Open

	with concurrent chemotherapy with escalating doses of capecitabine.		
AMAROS	After mapping of the axilla: Radiotherapy or Surgery: EORTC 10981-22023	Professor Robert Mansel	Open
ASTEC	A Randomised Trial of Lymphadenectomy and of adjuvant External beam Radiotherapy in the Treatment of Endometrial Cancer	Professor Henry Kitchener	Closed
BASO DCIS II	Randomised trial testing observation (no radiotherapy) against radiotherapy in women with low-risk completely excised ER positive ductal carcinoma in situ (DCIS) of the breast on adjuvant endocrine therapy.	Professor Nigel Bundred	Open
BC2001	2x2 Factorial Randomised Phase III Study comparing Standard versus Reduced Volume Radiotherapy with and without synchronous Chemotherapy in Muscle Invasive Bladder Cancer	Dr Robert Huddart, Professor Nicholas James	Open
BCON	A Multicentre Randomised Trial of Radical Radiotherapy with Carbogen in the Radical Radiotherapy of Locally Advanced Bladder Cancer	Professor Peter Hoskin	Closed
BNLI Radiation Dose	BNLI Randomised trial of radiation dose in non-Hodgkin's lymphoma	Professor Peter Hoskin	Closed
BNLI Stanford V	Protocol for a randomised phase III study of the Stanford V regimen, compared with ABVD for the treatment of advanced Hodgkin's disease	Professor Peter Hoskin	Open
BS06	A Randomised Study of Radical Radiotherapy in the Management of pT1G3 NxM0 Transitional Cell Carcinoma of the Bladder	Dr Stephen Harland	Closed
CHARTWEL	A Randomised Controlled Trial of CHARTWEL (a continuous hyperfractionated accelerated radiotherapy schedule) versus conventional radiotherapy in post-operative head and neck cancer patients.	Professor M Saunders, Professor S Dische	Closed
CHHIP	Conventional or Hypofractionated High Dose Intensity Modulated Radiotherapy for Prostate Cancer	Prof David Dearnaley	Open
CNS 1999 06	Treatment of children with newly diagnosed diffuse pontine gliomas using conventional radiotherapy and high dose tamoxifen	Dr Steve Lewis, Dr Antony Michalski	Closed
CNS 2001 06	(cisplatin, CCNU, vincristine) for metastatic (M1-3) Medulloblastoma	Dr Roger Taylor	Open

CNS 2003 05 (HIT-SIOP PNET 4)	A Prospective randomised controlled trial of hyperfractionated versus conventionally fractionated radiotherapy in standard risk medulloblastoma.	Dr Barry Pizer	Open
CNS 2004 01 (Supratentorial PNET)	Hyperfractionated accelerated Radiotherapy (HART) with chemotherapy (Cisplatin, CCNU, Vincristine) for non-pineal Supratentorial Primitive Neuroectodermal tumours CNS 2004 01	Dr Frank Saran	Open
CR07	A Randomised Trial Comparing Pre-Operative Radiotherapy and Selective Post-Operative Chemoradiotherapy in Rectal Cancer	Professor RJ Steele, Dr David Sebag-Montefiore, Professor Phil Quirke	Closed
EaStER Feasibility Study	Early Stage glottic cancer: Endoscopic excision or Radiotherapy - Feasibility study	Professor Martin Burchill	Open
EORTC 22922	Phase III randomized trial investigating the role of internal mammary and medial supraclavicular (IM-MS) lymph node chain irradiation in stage I-III breast cancer (Joint study of the EORTC Radiotherapy Cooperative Group and the EORTC Breast Cancer Cooperative Group EORTC 22922/10925)	Walter Van Den Bogaert	Closed
EORTC 22952	No Radiotherapy versus Whole Brain Radiotherapy for 1 to 3 Brain Metastases from Solid Tumor after Surgical Resection or Radiosurgery. A Randomized Phase III Trial.		In set-up
EORTC 22991	Three Dimensional Conformal Radiotherapy alone versus Three Dimensional Conformal Radiotherapy plus adjuvant hormonal therapy in localized T1b-c, T2a, N0, M0 prostatic carcinoma. A phase III randomized study.	Professor Malcolm Mason	Open
EORTC 55985	Phase II clinical trial on Taxol as single agent in locally advanced and/or metastatic or recurrent vulva cancer not amenable for surgery and/or radiotherapy	Professor John A Green	Closed
EORTC 62991	Phase II pilot of moderate radiotherapy for inoperable aggressive fibromatosis	Dr Martin Robinson	Open
EXTRA	Evaluation of Xeloda Treatment with radiotherapy in Anal Cancer	Dr Rob Glynn-Jones	Open
FAST	Prospective randomised clinical trial testing 5.7Gy and 6.0Gy fractions of whole breast radiotherapy in terms of late normal tissue responses and tumour control	Professor John Yarnold	Open
FORT	A phase III randomised controlled trial of low dose palliative radiotherapy for follicular lymphoma	Professor Peter Hoskin	Open

GRIN	A Phase III Study of Radical Radiotherapy with or without Gemcitabine in Patients with T1-2 N0-1 M0 Non-Small Cell Lung Cancer	Professor Allan Price	Open
High Dose Rhenium	High Activity Rhenium-186 HEDP with peripheral blood stem cell support in patients with bony metastases in prostate cancer.	Dr David Dearnaley, Dr Joe O`Sullivan	Closed
IMRT trial	Radiotherapy in early breast cancer: cosmetic outcome	Dr Margaret Moody	Open
LEG 2004 06 (Wilms tumour survivors)	Study to investigate lung function following pulmonary radiotherapy in Wilms tumour survivors (LEG 2004 06)	Dr Anthony Ng	Open
HNCRN5 1/2	A randomised 3-arm trial of modestly accelerated radiotherapy alone or with either synchronous nimerazole or synchronous cisplatinium chemotherapy	Dr M Robinson	In set up
HOT	Randomised phase II trial of hyperbaric oxygen therapy in patients with chronic arm lymphoedema after radiotherapy for early breast cancer	Professor John Yarnold	Open
IMPORT	IMRT in early breast cancer	Prof J R Yarnold	In set-up
INCH	A randomised phase II/III trial of induction chemotherapy followed by Continuous Hyperfractionated Accelerated Radiotherapy (CHART) versus CHART alone in patients with inoperable non-small cell lung cancer.	Dr Matthew Hatton	Open
MARS	Mesothelioma and Radical Surgery trial. MARS pilot study - to determine the feasibility and acceptability of performing a randomised trial comparing extra-pleural pneumonectomy (EPP) against no EPP surgery within the context of trimodality therapy (chemotherapy, surgery and radiotherapy)	Professor Tom Treasure, Professor Julian Peto, Mr David Waller	Open
PARSPORT	A multicentre randomised study of parotid sparing intensity-modulated radiotherapy in patients with head and neck cancer	Dr Chris Nutting	Open
PR07	A Randomised trial of Hormone Therapy plus Radical radiotherapy versus Hormone Therapy alone in Non-Metastatic Prostate Cancer	Professor Malcolm Mason	Open
PRIME	The PRIME breast cancer trial (postoperative radiotherapy in minimum-risk	Professor Robin Prescott	Open
PRIME II	Post-operative Radiotherapy In Minimum-risk Elderly Phase II	Dr Ian Kunkler	Open

Prostate HDR brachytherapy trial	Randomised trial of interstitial brachytherapy as a component of radical boost radiotherapy for localised prostatic cancer	Prof Peter Hoskin	Closed
Protect	The Protect Trial - Evaluating the effectiveness of treatment for clinically localised prostate cancer	Professor Jenny Donovan, Professor Freddie Hamdy, Professor David E Neal	Open
RACE	Radiation Complications and Epidemiology – Inherited factors contributing to radiotherapy side effects	Professor John Yarnold	Closed
RAPPER	Radiogenomics: assessment of polymorphisms for predicting the effects of radiotherapy	Dr Catherine West	Open
RIB	A multicentre randomised trial of single dose radiotherapy compared to Ibandronate for localised metastatic Bone pain	Prof Peter Hoskin	Open
RT 2002 02	Comparison of Hair regrowth in children with localised PNET's of the posterior fossa (medulloblastoma) treated with surgery followed by radiotherapy or chemotherapy and radiotherapy	Dr Frank Saran	Open
RT With Weekly GEM (temp acronym)	Phase II study of radiotherapy with concurrent weekly gemcitabine in muscle-invasive bladder cancer	Dr Richard Cowan	Open
SC20	A phase III international randomised trial of single vs multiple fractions of re-irradiation of painful bone metastases.	Prof Peter Hoskin	Open
SECRAB	Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast Cancer	Dr I Fernando	Closed
Skin Study	A Randomised, Double-Blind Controlled Trial of Mometosone Furoate Cream Versus Placebo to Prevent Radiation Dermatitis of the Breast and Chest Wall	Dr Andrew Hindley	In Set-up
SOCCAR	A randomised phase III trial of sequential chemotherapy followed by radical radiotherapy versus concurrent chemo-radiotherapy followed by chemotherapy in patients with inoperable stage III non-small cell lung cancer and good performance status	Dr Joe Maguire	in set-up
START	Standardisation of Breast Radiotherapy (START) Trial	Professor John Yarnold	Closed

Supratentorial PNET	Hyperfractionated accelerated Radiotherapy (HART) with chemotherapy (Cisplatin, CCNU, Vincristine) for non-pineal Supratentorial Primitive Neuroectodermal tumours CNS 2004 01	Dr Frank Saran	Open
SUPREMO	Selective use of postmastectomy radiotherapy after mastectomy	Dr I Kunkler	Open
VORTEX VORTEX BIOBANK	Randomised trial evaluating impact of changes in dose & volume of postoperative radiotherapy on morbidity and limb function in adult patients with extremity soft tissue sarcoma with translational study (Vortex Biobank)	Dr Martin Robinson	In Set-up
Wilms Tumour Survivors (LEG 2004 06)	Study to investigate lung function following pulmonary radiotherapy in Wilms tumour survivors (LEG 2004 06)	Dr Anthony Ng	Open

Professor Peter Hoskin, Chair