

NCRI Lung Clinical Studies Group

In the last year the new group structure has started working. The studies outlined below are presented by sub-group. We have also taken soundings from colleagues around the country and particularly at the annual BTOG meeting about the workings of the NCRI Lung CSG. The general feeling was that there needed to be a simple process by which new trial proposals could be assessed. We organised a meeting with representatives of BTOG, LLCG, the Manchester lung group, the Birmingham lung group and the NCRI Lung CSG. The new trial proposals document will be circulated widely. As part of the governance of this process we are developing joint BTOG/NCRI Lung CSG open meetings for each of the subgroups at the annual BTOG meeting. These meetings will discuss all applications to the subgroup along with their progress and the future strategy of the sub-group. 4 members have left the Group and 5 new members were appointed.

Portfolio and accrual

Our current portfolio is as follows:

SCEPTRE (Chair: Mike Peake)

The key tasks for this sub-group are to re-examine the possibility of screening trials and to develop smoking cessation studies.

Acronym	Title	PI(s)	Status
Early Lung Cancer Study	The use of molecular biomarkers in early lung cancer detection	Professor John Field	Open
ReSoLuCENT	Resource for the Study of Lung Cancer Epidemiology in North Trent	Prof. Panella Woll	Open

Rare Tumours (Chair: Stephen Falk)

This group will start developing trials for rarer thoracic malignancies for which few data currently exist and where there is a particular opportunity for national trials.

Translational Research (Chair: John Field)

GELCAPS completed accrual in the past year and this will inevitably be reflected in patient accrual numbers for the Lung CSG. The particular roles of this sub-group will be 1) to ensure that we maximise the translational potential of trials in the portfolio and 2) to conduct observational studies such as those noted below.

Acronym	Title	PI(s)	Status
CLUB	Cancer of the Lung Biomarkers	Professor Nicholas James	Open
GELCAPS	Genetic Lung Cancer Predisposition Study: a molecular epidemiology study	Dr Tim Eisen	Closed
LLP	LLP Liverpool Lung Project	Professor John Field	Open

Mesothelioma (Chair: David Waller)

David Waller has already built a successful mesothelioma portfolio and the new structure should facilitate further developments.

Acronym	Title	PI(s)	Status
Julian Peto's Mesothelioma and Lung Cancer Study (MALCS)	A population based case-control study of mesothelioma and lung cancer in relation to occupation among British men and women under the age of 60	Professor Julian Peto	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, post-operative radiotherapy).	Professor Julian Peto, Mr David Waller, Professor Tom Treasure	Open
MS-01	A randomised controlled trial of active symptom control with or without chemotherapy in the treatment of patients with malignant pleural mesothelioma	Dr Martin Muers	Open
VATS	Prospective randomised controlled trial of video-assisted thoracoscopic (VATS) cytoreductive pleurectomy compared to talc pleurodesis in patients with suspected or proven malignant mesothelioma.	Dr Clare Laroche, Mr AJ Ritchie, Dr Robert Winter	Open

NSCLC I-III & SCLC LD (Chair: Allan Price)

Allan has being very pro-active in developing radiotherapy trials and now chairs this sub-group focusing on treatments with radical intent.

Acronym	Title	PI(s)	Status
FRAGMATIC	A randomised phase III clinical trial investigating the effect of FRAGMin Added to standard Therapy In patients with lung Cancer	Dr Fergus MacBeth	In Set-up
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
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	In set-up
LU22	A randomised trial of surgical resection with or without pre-operative chemotherapy in patients with operable non-small cell lung cancer (NSCLC) of any stage	Mr Peter Goldstraw, Ms Penelope Hopwood, Dr Marianne Nicolson, Professor Ian Smith	Closed
MUSICAL	Mediastinal endoscopic UltraSound In the diagnosis and staging of CArcinoma of the Lung	Dr Steve Pereira	Open
QUARTZ	A phase III multicentre randomised controlled trial to assess whether optimal supportive care (including dexamethasone) alone is as effective as optimal supportive care (including dexamethasone) and whole brain radiotherapy (WBRT) in the treatment of pati	Dr Paula Mulvenna	In Set-up
SOCCAR	A randomised phase III trial of sequential	Dr Joe Maguire	In set-up

	chemotherapy followed by radical radiotherapy versus concurrent chemoradiotherapy followed by chemotherapy in patients with inoperable stage III non-small cell lung cancer and good performance status.		
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NSCLC IIIB/IV & SCLC ED (Chair: David Ferry)

David has taken on this sub-group which accounts for the majority of recruitment into treatment trials.

Acronym	Title	PI(s)	Status
BTOG2	British Thoracic Oncology Group (BTOG) phase III trial of gemcitabine plus cisplatin at 80 mg/m ² vs gemcitabine plus cisplatin at 50mg/m ² gemcitabine plus carboplatin AUC 5 in stage IIIB/IV non small cell lung cancer (NSCLC)	Dr David Ferry	Open
GEM Hospitalisation	A pragmatic, randomised study to compare the hospitalisation rates of two platinum-based outpatient regimens (gemcitabine/cisplatin vs. gemcitabine/carboplatin) in non-small cell lung cancer (NSCLC).	Professor Nick Thatcher	Open
LLCG Study 12	A phase III randomised, double-blind, Placebo controlled trial of Carboplatin/Etoposide with or without Thalidomide in small cell lung cancer	Dr S M Lee	Open
LLCG Study 14	A phase II/III randomised, double blind, placebo controlled trial of Gemcitabine/ Carboplatin with or without Thalidomide in advanced non-small cell lung cancer	Dr S M Lee	Open
LungStar	A multicentre phase III randomised double blind placebo controlled trial of pravastatin added to first-line standard chemotherapy in patients with small cell lung cancer	Prof M J Seckl	In Set-up
Nebulised Furosemide	Does nebulised furosemide improve severe breathlessness in patients with lung cancer?	Dr Andrew Wilcock	Open
Topical	Tarceva or placebo in clinically advanced non-small cell lung cancer	Dr Siow Ming Lee	Open
TRANSMATIC	A pilot study to assess the utility of quantitative methylation specific PCR (Q-MSP) in the quantitative identification of cancer cell dissemination in the peripheral circulation of lung cancer patients	Dr Fergus Macbeth	In Set-up

Accrual to lung studies was 3.4% of incidence cases (1183 patients). Two new studies were funded at the June 2006 CTAAC meeting, SEARCH – a randomised control trial of surveillance for the early detection of lung cancer in a high risk group, and ADMINM – a randomised stratified phase II multicentre clinical trial of single agent ADI-PEG20 (pegylated arginine deiminase) in patients with malignant pleura mesothelioma, both of which should increase recruitment in 06/07.

The following studies closed before period under review:

Acronym	Title	PI(s)	Status
BLT	A randomised trial of cisplatin-based chemotherapy for patients with all stages of non-small cell lung cancer.	Ms N Gower	Closed
DOCMIC	A Randomised study of Docetaxol with Carboplatin vs Mitomycin, Vinblastine, Cisplatin (MVP) or Mitomycin, Ifosfamide and Cisplatin (MIC) in Inoperable Advanced Non Small Cell Lung Cancer	Prof. N Thatcher	Closed
Fitness for surgery	Prospective study to assess the ability of the new BTS guidelines to assess fitness for surgery in patients undergoing lung resection for lung cancer	Dr C Laroche, Dr T Win	Closed
LLCG Study 10	A Phase III randomised comparison of gemcitabine/carboplatin with cisplatin/etoposide in small cell lung cancer	Dr R Rudd	Closed
LLCG Study 11	A Phase III randomised comparison of Gemcitabine/Carboplatin (GC) with Mitomycin/Ifosfamide/Cisplatin (MIC) in non-small cell lung cancer (NSCLC)	Dr R Rudd	Closed
LU21	Randomised Clinical Trial of Ifosfamide, Carboplatin and Etoposide with Mid-Cycle Vincristine (VICE) versus Standard Practice Chemotherapy in Patients with Limited Small-Cell Lung Cancer (SCLC) and Good Performance Status	Prof. N Thatcher	Closed
MESO-1	Randomised feasibility study of active symptom control with or without chemotherapy in the treatment of patients with mesothelioma	Dr M Muers	Closed
ThalidomideSCLC	Thalidomide in Small Cell Lung Cancer		Closed
TIME	Time to consult with symptoms of lung cancer: Is it related to deprivation or rurality		Closed
TR8SCLC	A Randomised Study of Timing of Thoracic Irradiation in Small Cell Lung Cancer		Closed

Future priorities

In the next year we aim to develop further studies to fill identified gaps in our trials portfolio.

Other activities

Members of the CSG actively participate in the Lung SPG. The Group held a successful session at the October 2005 NCRI Cancer Conference.

Professor Tim Eisen, Chair