

LCTU NEWSLETTER

Cancer Research UK Liverpool Cancer Trials Unit



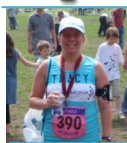
MERRY CHRISTMAS





Christmas Randomisation Cover

Page 2



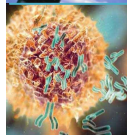
Fundraising Update

Page 2



Open and recruiting trials

Page 3



Trials in setup

Page 4



Trials closed to recruitment

Page 5



Translational & LECMC

Page 5



Staff Update & Notices

Page 6



Contact Information

Page 7

Christmas Randomisation Cover

24th - 28th December: No Randomisations - LCTU closed

29th - 31st December: See trial specific information below

1st - 4th January: No Randomisations - LCTU closed



	29/12/2008	30/12/2008	31/12/2008
HOPON	Ring coordinator on 07514695738 if you would like to randomise or if you wish to report an SAE		
ITEM	Ring coordinator on 07514695738 if you would like to randomise or if you wish to report an SAE		
ESPAC-4	No Randomisations	Ring Rob Hanson on 07779871269 if you wish to randomise. Any SAEs will also be picked up today	No randomisations
TELOVAC	Please ring Carl Henry on 07990 966996 if you wish to randomise		
EUROPAC2	No randomisations		

Fundraising Update

We recently received an update from the Events team at Cancer Research UK concerning the Race for Life Events in Merseyside which the LCTU supported.

The events in this area and also in Staffordshire raised over £1.1million which is a fantastic amount. Cancer Research UK fund pioneering research so we are very keen to get involved and help out wherever we can

The 2009 events are now being arranged for dates please see details on the right. If you would like to take part please visit www.raceforlife.org

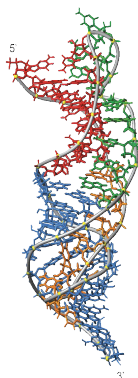
Location	Date	Time
Sefton Park	31st May	11am
Chester City	14th June	9am
St Helens	17th June	7.30pm
Wirral	5th July	11am
Knowsley	14th July	7.30pm
Aintree	19th July	11am & 2pm
Wirral 10k	18th Oct	11am

TeloVac Update

Once again, the team would like to thank everyone who has contributed to the success of the study so far and look forward to working with sites who are in the set-up phase.

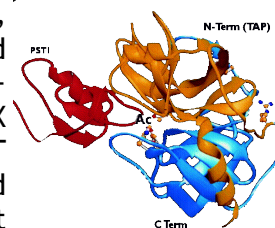
We have reached 25% recruitment in November with a current accrual of 280 patients, thanks for everyone's hard work. All recruiting sites will soon receive a form which will enable them to order Capecitabine for use in TeloVac directly from Roche.

We now have eight sites taking part in Immunomonitoring and future analysis and we have received a number of samples. We have more sites in set up, and hope to open them for sample collection soon. If any sites wish to take part in sample collection then please contact the TeloVac co-ordinator.



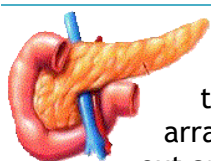
EUROPAC2

EUROPAC2 is a multi-centre, double blind, randomised controlled trial to investigate the efficacy of ANOTX (vers) 1.2 and MGCT (Magnesiocard®) compared to placebo in the treatment of pain in patients with hereditary pancreatitis and idiopathic chronic pancreatitis.



This trial aims to recruit 240 patients aged between 5 -65 years old that have been diagnosed with HP or ICP. We have currently recruited 12 Patients within the UK, taking total recruitment across Europe to 72. The LCTU is currently looking to open more centres within the UK, if your hospital is interested in taking part in the trial please contact the trials unit for more information.

ESPAC-4 Update



ESPAC-4 opened to recruitment at the Royal Liverpool and Broadgreen University Hospital and Clatterbridge Centre for Oncology in October and the first patient was randomised on the 10th November 2008. Currently we are working on open sites across the UK and hope to arrange site initiations early in the new year. Research Site Agreements are currently being sent out and final 'green light' requirements are being finalised for many of the Research Sites.

ESPAC is an international collaboration and we are working with our international colleagues to open the study across Europe, Japan and Australia. A study initiation meeting is planned in Sweden for early February and other countries are seeking a co-sponsor and possible funding for the study. We are looking to promote the study across Europe and the rest of the world.

If you would like more information or would like to take part in ESPAC-4 please contact the trial coordinator Charlotte Rawcliffe (contact details on back page) or visit the LCTU website www.lctu.org.uk

Open and recruiting trials - Phase II

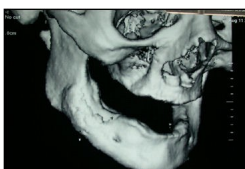
HOPON

HOPON is a two year study looking at hyperbaric oxygen in the prevention of osteoradionecrosis following at risk surgical procedures on irradiated mandibles in comparison with standard management involving antibiotics and mouthwashes.

HOPON is open to recruitment in Liverpool with the University Hospital Aintree, the Royal Liverpool Dental Hospital and the hyperbaric unit (North West Emergency Recompression Unit) at Murrayfield Hospital and has so far recruited 4 patients. The following sites are all about to be given the go-ahead to open to recruitment: Aberdeen Royal Infirmary, Leeds, North of England Medical Hyperbaric Unit (Hull), Yeovil Hospital and The Hyperbaric Medical Centre (Plymouth). Research Site Agreements are now being developed between the

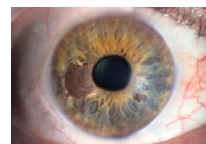
Sponsors and other participating sites and further sites will also be involved shortly including Manchester, Gloucester, Derriford and Portsmouth.

For more information contact the Trial Co-ordinator Matthew Bickerstaff (contact details on back page) or visit the LCTU website www.lctu.org.uk



ITEM

ITEM is a single arm phase II study of Imatinib in good performance status patients with c-Kit positive metastatic Uveal Melanoma. ITEM is open to recruitment at Clatterbridge Centre for Oncology, Mount Vernon Hospital, Weston Park Hospital and St James's University Hospital.



A total of 14 patients are required in the first stage before an interim analysis is carried out. This will help to determine whether the trial will continue to recruit up to a maximum of 25 patients. A MACRO database and a Trial Management System are in place. For more information contact the Trial Co-ordinator Matthew Bickerstaff (contact details on back page) or visit the LCTU website www.lctu.org.uk

Trials in setup/awaiting funding confirmation

PACIFICO

(Purine-Alkylator Combination In Follicular lymphoma Immuno-Chemotherapy for Older patients)

PACIFICO* (previously known as RiCh FLO) is a new phase III randomised controlled trial comparing two different immuno-chemotherapy regimens in patients with Follicular Lymphoma (FL) aged 60 years or over (or less than 60 but more intensive chemotherapy considered inappropriate due to co-morbidity).

Older patients are increasingly underrepresented in trials of FL owing to the increasing intensiveness of the treatment regimens used. PACIFICO will investigate a new combination regimen, R-FC (rituximab, fludarabine, cyclophosphamide) that, when used appropriately, is felt to be both safe and highly effective in the treatment of FL and avoids using cardiotoxic drugs such as adriamycin or mitoxantrone.

The trial will compare R-FC to the current gold standard treatment R-CVP (rituximab, cyclophosphamide, vincristine, prednisolone), with primary outcomes of Progression Free Survival and Toxicity. Responders in both groups will receive 2 years of rituximab maintenance, which will be provided free charge. The study aims to recruit a total of 680 patients, and it is hoped that as many UK sites as possible will participate.

The Chief Investigator is Andrew Pettitt, Trial Coordinator Stacey Carruthers and Data Manager James Dodd. The team is working hard to get the study launched as quickly as possible, and it is hoped that the first patient will be recruited spring 2009.

If you require any further information regarding the PACIFICO trial, please contact the trial coordinator Stacey Carruthers on 0151 794 8897 or e-mail scar1@liv.ac.uk.

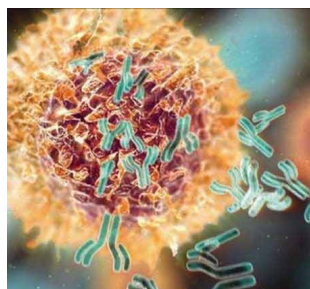
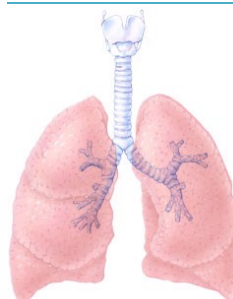


Image shows Rituximab binding to a cell surface

UK Lung Screening Trial



Lung cancer kills more people worldwide than any other malignancy and currently 33,500 individuals die each year in the UK from lung cancer. The number of deaths has fallen in the past years and this is likely to be due to a decline in tobacco smoking, and possibly greater public awareness.

However, there is now a large population of ex-smokers in the UK, who remain at high risk of developing lung cancer; dependent on their smoking duration prior to tobacco cessation. This group of individuals will continue to be at risk over the next two to three decades. The evaluation of lung cancer screening is urgently required, as surgical resection at an early stage of the disease remains the only realistic option for a cure.

The NIHR Health Technology Assessment Programme (HTA) has funded the Feasibility and Protocol development of the UK Lung Cancer CT Screening trial (UKLS). We are currently developing questionnaires, protocols, and costing models for a pilot trial which will be resubmitted to the HTA in March 2009.

The UKLS will be a randomised controlled trial of CT scanning against no intervention. The Pilot will involve 500 screened individuals over 15 months. The screening workload and schedule in the Main Trial will depend on the experience in the pilot and the capacity of the trial centres.

ESPAC-3(v2)

The final patient was recruited in May 2008 and has now completed treatment, the current focus for the study is to concentrate on collecting follow-up and Quality of Life forms. We have been working hard in the unit to input data on to the database, generate data queries and chase missing forms. The preliminary analysis of the ductal patients is planned for early in the new year and a late breaking abstract is intended for ASCO 2009. During the data lock we will be in touch with sites where essential data required for the analysis is missing.

There have also been several successful international study visits to Italy, Germany and Canada in the and we would like to thank those involved for their hospitality and help regarding the ESPAC-3(v2) data.

Many thanks to everyone working on the study for their help with data collection effort.

GEMCAP

We are now in the process of archiving the GEMCAP data. We have recently sent a letter to sites with details and processes.



Translational and Liverpool ECMC

Liverpool Experimental Cancer Medicine Centre

A major network of Experimental Cancer Medicine Centres (ECMCs) has been established across the UK to drive the development of biomarkers and new anti-cancer treatments.

The aim of the ECMC Network is to bring together laboratory and clinical patient-based research to speed up the development of new therapies and biomarkers by evaluating new drugs and individualising patient treatment. More information on the ECMC initiative and other ECMC centres can be found at the recently launched ECMC website <http://www.ecmcnetwork.org.uk/>.



Karl Harvey has recently taken over as Liverpool ECMC Coordinator (contact details on back page). Karl is in the process of reviewing current systems and will be in touch with trial staff to discuss ways to improve and streamline patient recruitment and sample collection reporting.

We currently have 52 adopted trials and 15 to be adopted. For more information please visit the Liverpool ECMC website www.lctu.org.uk/lecmc/

ESPAC-Tplus

ESPAC-Tplus was funded by the Translational Research in Clinical Trials Committee (TRICC) of Cancer Research UK in order to enable high quality translational research to be embedded in the ESPAC trials. ESPAC-Tplus is designed to allow both prospective and retrospective sample collection and analysis.

ESPAC-Tplus has now collected over 600 samples from sites who participated in the ESPAC trials. The table on the right shows breakdown of samples received by country.

The following UK sites have received approval; The Royal Liverpool & Broadgreen University Hospitals Trust, Clatterbridge Centre for Oncology, James Cook University Hospital, North Manchester General Hospital, St James's University Hospital, Torbay Hospital and Yeovil Hospital

Country	Paraffin Embedded	Frozen	Blood
UK	104	77	11
Germany	58	48	
Greece	26		
Italy	99		
Canada	31		
Total	318	125	11

If any sites are experiencing any problems or would like more information please contact Tracy Ball (contact details on back page)

Staff Update

Since our last newsletter we have two new additions to the LCTU team. We welcome Stacey Carruthers as the new PACIFICO trial coordinator and James Dodd as the PACIFICO Data Manager.

We bid farewell to Ben Hardwick who will be leaving at Christmas to begin a trial coordination post at the MCRN in January and Catrin Tudur Smith who left on the 1st December to work as a Senior Lecturer at the MRC hub for Trial methodological research. We wish them both the best of luck.

Karl Harvey will be taking over the coordination of the LECMC. For more information on the LECMC see the update above or visit the website www.lctu.org.uk/lecmc.



*James Dodd
(PACIFICO Data
Manager)*



*Stacey Carruthers
(PACIFICO Trial
Coordinator)*

Big Thanks

The LCTU would like to thank all the researchers, nurses, investigators and other staff for all their hard work and cooperation over the last year. We hope next year is just as successful!

Patient Liaison Representative

If you are interested in becoming a patient liaison representative for patients in the TeloVac trial or other studies run through the LCTU; or if you are aware of anyone that would be interested please email lctu@liverpool.ac.uk

A patient liaison representative will be an independent advocate for patients.

Consumer Involvement

We are looking for people who can get involved with our cancer research and the way that our trials are run. If you have suffered from cancer or know of someone that has, and you would like to get involved please contact us using the details below. We would be delighted to hear from you.

Liverpool Cancer Trials Unit Vision

- ◆ The LCTU works closely with Cancer Research UK in the Clinical Research of new and existing products for the treatment of cancer, easing suffering and improving the quality of life of these patients.
- ◆ The LCTU is recognised for having a positive impact on peoples' lives, meeting the needs and surpassing external expectations with the services we offer.
- ◆ The LCTU offers a dynamic workplace in which people can realise their professional ambitions while being involved in a dedicated team to Clinical Research.

LCTU STAFF AND CONTACT INFORMATION

Director - Professor John Neoptolemos (j.p.neoptolemos@liverpool.ac.uk)
Assistant Director - Paula Ghaneh (p.ghaneh@liverpool.ac.uk)
Acting Operational Director - Julia West (Julia.west@liverpool.ac.uk)
Lecturer in medical statistics - Susanna Dodd (s.r.dodd@liverpool.ac.uk)

EUROPAC2 Coordinator—Gemma Welsh (g.welsh@liverpool.ac.uk)
EUROPAC Research Fellow - Jane Butler (j.v.butler@liverpool.ac.uk)
EUROPAC Database Manager - Matthew Harcus (mjharcus@liverpool.ac.uk)

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TeloVac Monitor - Joanne Eatock (j.eatock@liverpool.ac.uk)
TeloVac Monitor - Gemma Padgett (g.a.padgett@liverpool.ac.uk)
TeloVac Data Manager - Hayley Jelleyman (h.e.jelleyman@liverpool.ac.uk)
TeloVac Data Manager - Alan English (a.j.english@liverpool.ac.uk)

PACIFICO Coordinator - Stacey Carruthers (Stacey.carruthers@liverpool.ac.uk)
PACIFICO Data Manager - James Dodd (j.p.dodd@liverpool.ac.uk)

ITEM & HOPON Coordinator—Matthew Bickerstaff (oasis@liverpool.ac.uk)

Lung Cancer Screening Coordinator - Chris Smith (c.smith6@liverpool.ac.uk)

ESPAC Coordinator - Charlotte Rawcliffe (c.rawcliffe@liverpool.ac.uk)
International Monitor - Rob Hanson (r.hanson@liverpool.ac.uk)
ESPAC-4 - Data Manager - Karl Harvey (karl.harvey@liverpool.ac.uk)
Data Clerk - Paul Thompson (Paul.thompson@liverpool.ac.uk)

Liverpool ECMC Coordinator - Karl Harvey (karl.harvey@liverpool.ac.uk)
Liverpool ECMC Research Nurse - Rosie Davies (Rosalyn.davies@liverpool.ac.uk)
Liverpool ECMC Research Nurse - Jan Davies (janet.davies@liverpool.ac.uk)
Liverpool ECMC Laboratory technician - Alex Ciupa (a.ciupa@liverpool.ac.uk)

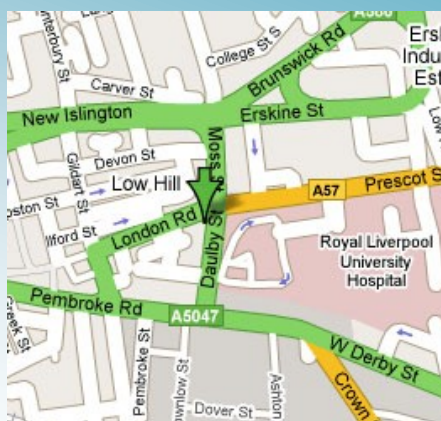
ESPAC-Tplus Trial Support Officer - Tracy Ball (tracyb@liverpool.ac.uk)
ESPAC-Tplus technician - Liz Garner (Elizabeth.garner@liverpool.ac.uk)
Database Developer - Laura Marsh (l.marsh@liverpool.ac.uk)
Administrator/Data Clerk - Wendy Scragg (Wendy.scragg@liverpool.ac.uk)
Research Fellow - Richard Smith (r.smith11@liverpool.ac.uk)
Clinical Research Officer - Seema Chauhan (seema.chauhan@liverpool.ac.uk)
Research Practitioner - Catherine Whittemore (c.whittemore@liv.ac.uk)

LCTU Website & Email

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LCTU ADDRESS AND LOCATION



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SP08 SPORTS PERSONALITY



Liverpool hosts the BBC Sports Personality of the Year. Some highlights from this year: March—Oxford beat Cambridge, Team GB returning from a successful Olympics in Beijing



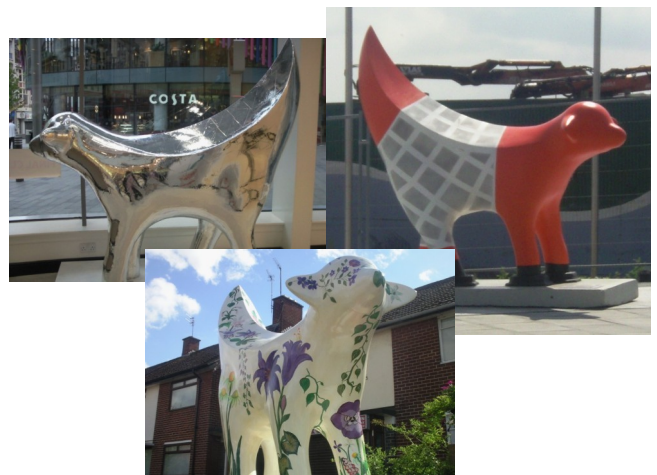
November saw Liverpool hosting the annual MTV European Music Awards



La Princesse, a giant metal spider makes its way through the streets of Liverpool



July - Liverpool hosts the Tall Ships Races.



16th June—25th August,
No one can forget the
Superlambananas



LCTU

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CANCER RESEARCH UK

