

NEWSLETTER

Welcome to the fifth edition of the Liverpool Cancer Trials Unit Newsletter.

Clinical Trials Research Centre Gains UKCRC Registration

Following a review by an international panel, the University of Liverpool Clinical Trials Research Centre (CTRC) has been assessed as reaching the highest quality standard required by the UK Clinical Research Collaboration (UKCRC). The UKCRC (www.ukcrc.org.uk) is a partnership working to establish the UK as a world leader in clinical research.

The CTRC encompasses the Liverpool Cancer Trials Unit, the Medicine for Children Clinical Trials Unit and clinical trial staff from epilepsy, dental science, obstetrics and gynaecology. The CTRC represents trials activity in distinct clinical areas - cancer, medicines for children, epilepsy, dental science, obstetrics and gynaecology. The standards set for UKCRC Clinical Trials Unit Registration were very high and demonstrable evidence that a Unit fulfilled the criteria for all the key competencies was considered essential. 26 units were given full registration with a further 14 units given provisional registration.

The Director of the CTRC, Professor Paula Williamson said: *"I believe Liverpool is extremely well-placed with this initiative to contribute to significant improvements in health."* Paula is pictured here (bottom centre) with other members of the CTRC.

Back row l-r: Catrin Tudur-Smith - Senior Lecturer in Medical Statistics, Chris Braithwaite - IT Administrator, Helen Hickey - Senior Trial Coordinator at the MCRN and Emily Owen - Operational Director/Senior Trial Coordinator at the LCTU.

Front row l-r: Carrol Gamble - Senior Lecturer in Medical Statistics, Paula Williamson - Director of the CTRC and Girvan Burnside - Lecturer in Dental Statistics



Cancer Research UK awards funding for RiCh FLO

RiCh FLO (Phase III multicentre trial comparing two different Rituximab-Chemotherapy induction regimens for Follicular Lymphoma in Older patients): Follicular lymphoma predominantly affects the elderly, yet the optimum treatment for older patients with the disease has not been defined. The present study aims to address this question by comparing the drug combination that is currently considered the gold-standard (R-CVP) with a newer combination (R-FC) that might be more effective. Outcomes to be assessed are response rates, progression-free survival, overall survival, toxicity, quality of life and cost effectiveness.

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IMPORTANT NOTICES

Emily Owen the Trial Co-ordinator of ESPAC-3(v2) would just like to inform everyone that the ampullary arm of the trial is still recruiting. There are 7 patients left to be recruited before the trial closes to recruitment completely.

Just a small note to wish all our support to Tracy Ball and Liz Garner who will be running the Liverpool Women's 10k on the 11th May. Tracy and Liz will be raising money for Cancer Research UK. If you would like to donate please visit:
<http://www.justgiving.com/tracyandliz>



HOPON

HOPON is a two year study looking at hyperbaric oxygen to prevent osteoradionecrosis following at risk surgical procedures on irradiated mandibles.

In order to comply with the relevant regulations, MREC and CTA approvals have been completed and submitted.

CRFs are being developed and on completion these will be transferred into a MACRO data-

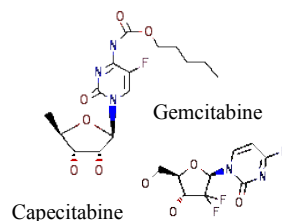
base. A Trial Management System has also been setup. The trial is hoping to open at the end of April. This trial is currently being coordinated by Emily Owen, but a position for a HOPON/ITEM coordinator has been advertised and will hopefully will be filled soon!



ESPAC-4

ESPAC-4 is a two arm open-label, phase III, multi-centre international randomised control trial. The aim of this trial is to compare length of survival following resection and either adjuvant gemcitabine plus capecitabine or gemcitabine alone in patients with pancreatic ductal adenocarcinoma. After alterations to the protocol, this was resubmitted to MREC and MHRA. A positive response has now been received from the MHRA. CRFs have now been developed and are in the process of being transferred onto the MACRO database.

The trial is currently being co-ordinated by Emily Owen; however a new Co-ordinator has been appointed and will be starting soon.



ESPAC-3(v2) Trial Update

******AMPULLARY/OTHER ARM OF THE TRIAL STILL OPEN TO RECRUITMENT******

There are 7 ampullary patients still required to be randomised to reach the target figure of 300. Data collection continues in anticipation of an interim analysis of the ductal adenocarcinoma group. If you have any outstanding data please send it in ASAP.



ESPAC-Tplus

Congratulations to Heidelberg who are the first non-UK site to send us their samples. Combined with the samples from Liverpool we now have over 200 tissue samples stored in the GCLP labs. Many sites are in the process of obtaining R&D and ethical approval.



Note: Site-specific assessment (SSA) is not a requirement for ethical review as ESPAC-Tplus is a research tissue bank.

EUROPAC2 Trial Update

EUROPAC2 has now randomised ten patients taking the total recruited across Europe to 62. The trial is aiming to recruit a total of 240 patients between the two co-ordinating centres.



If you have any patients who may benefit from the EUROPAC2 trial please contact Gemma by email gwelsh@liv.ac.uk.

GemCap Trial Update

The GemCap trial is now in the final stage and data analysis is taking place. We expect results to be published later this year. Site closeouts are now being carried out by the LCTU monitors and are being co-ordinated by Julia West. If you have any queries please contact Julia by email: Julia.west@liverpool.ac.uk

LECMC - Update and Latest News

The Liverpool ECMC have recently appointed two Research Practitioners. They have joined us from the department of Haematology at the Royal Liverpool and Broadgreen University Hospital and Clatterbridge Centre for Oncology. The LECMC continues to adopt and support trials in a range of disease areas. Most recently CytImmune - Cyt-6091 has been adopted. The LECMC would like to welcome Chris Holcombe and Sarah Coupeland to the Management Board. The LECMC now has a separate website from the LCTU. This will be online in the coming months. Please link to the LECMC website from the LCTU homepage.

LECMC - Liverpool Experimental Cancer Medicine Centre

About the LECMC | LECMC Trials | Facilities | Useful Links | Latest News

About the LECMC

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Background of the LECMC

Experimental Cancer Medicine Centres are a joint initiative between Cancer Research UK and the departments of health in England, Scotland and Wales. Its funding replaces NTRAC support and provides infrastructure support for staff and running costs to underpin early phase trials and translational research.

The Liverpool Experimental Cancer Medicine Centre has been awarded to the University of Liverpool (School of Cancer Studies and Pharmacology) and the NHS partners of the Royal Liverpool and Broadgreen University Hospital and Clatterbridge Centre for Oncology.

TeloVac Update and Latest News

As can be seen the TeloVac team has grown in strength since our last communication with the addition of Ben, Hayley and Alan (Data Managers) and Rob (International Trials Monitor). The team are also delighted to confirm that TeloVac is well and truly in the recruitment phase with 120 patients randomised across 35 centres. We are all delighted with the feedback the team are getting from the active sites. Monitors are now hoping to visit all sites on a regular basis to help iron out any issues encountered and bring the data back to the LCTU.



Immuno-Monitoring:

We expect to invite selected sites (ECMC) to take part in the immune-monitoring study within TeloVac in the next couple of months and will distribute the equipment and SOPs/Flow Charts to help explain the process. There will be a full announcement nearer the time.

All the team would like to thank everyone who has contributed to the success of the study so far and look forward to working on sites who are in the set-up phase. There will be a TeloVac newsletter on its way to you but please feel free to contact the team at any time if you have a question.



ITEM - Latest news and Update



ITEM is a single arm phase II study of Imatinib in good performance status patients with c-Kit positive metastatic Uveal Melanoma. In compliance with the necessary regulations, MREC and CTA approvals have been completed and submitted. Approval for these is expected within a month. Sites to run the trial have been identified and approached and are currently getting the necessary approvals from their R&D Department and their Local Research Ethics Committees. CRFs have been designed, the Trial Management System has been set up and the MACRO database is in development. The trial is hoping to open April/May.

For more information contact Julia West (see back page for contact details). Julia is currently the Trial Co-ordinator but a position for a HOPON/Item Co-ordinator has been advertised and will be appointed soon.

Staff Update

Since our last newsletter there have been several staff changes. We bid a sad farewell to Michelle Mossa the Unit Manager and Emily Owen has been promoted to Operational Director of the LCTU. A new ESPAC Co-ordinator has been appointed and will start soon.

We welcome four new data managers; Ben Hardwick (TeloVac), Hayley Jelleyman (TeloVac), Alan English (TeloVac) and Karl Harvey (ESPAC-4); an International Monitor, Rob Hanson and an ESPAC-Tplus laboratory technician, Liz Garner. In order to accommodate all these new members of the team the LCTU will be moving to a bigger office sometime in April.

This picture taken just before Christmas 2007 shows how large the team has grown over the past two years. At the beginning of 2006 there were 6 members of staff. At the beginning of 2008 there are 29 member of staff— an increase of over 400%!



LCTU STAFF AND CONTACT INFORMATION

Director - Professor John Neoptolemos (j.p.neoptolemos@liverpool.ac.uk)
Assistant Director - Paula Ghaneh (p.ghaneh@liverpool.ac.uk)
Operational Director - Emily Owen (e.owen@liverpool.ac.uk)
Senior Lecturer in medical statistics - Catrin Tudur-Smith (cat1@liverpool.ac.uk)
Lecturer in medical statistics - Susanna Dodd (s.r.dodd@liverpool.ac.uk)

EUROPAC2/LECMC Coordinator - Gemma Welsh (gwelsh@liverpool.ac.uk)
EUROPAC Research Fellow - Chris Grocock (c.j.grocock@liverpool.ac.uk)
EUROPAC Database Manager - Matthew Harcus (mjharcus@liverpool.ac.uk)

TeloVac/GemCap Coordinator - Julia West (Julia.west@liverpool.ac.uk)
Senior Monitor - Carl Henry (c.henry@liverpool.ac.uk)
TeloVac Monitor - Joanne Eatock (j.eatock@liverpool.ac.uk)
TeloVac Data Manager - Ben Hardwick (b.hardwick1@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)

ESPAAC Coordinator - Charlotte Rawcliffe (email TBA)
International Monitor - Rob Hanson (r.hanson@liverpool.ac.uk)
ESPAAC-3 (v2) Data Manager - Matthew Bickerstaff (oasis@liverpool.ac.uk)
ESPAAC-4 - Data Manager - Karl Harvey (karl.harvey@liverpool.ac.uk)
Data Clerk - Paul Thompson (Paul.thompson@liverpool.ac.uk)

LECMC Research Nurse - Rosie Davies (email TBA)
LECMC Research Nurse - Jan Davies (email TBA)
LECMC Laboratory technician - Alex Ciupa (a.ciupa@liverpool.ac.uk)

Trial Support Officer - Tracy Ball (tracyb@liverpool.ac.uk)
ESPAAC-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)

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.

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.

Job Vacancies

Clinical Trials Coordinator
Clinical Trials Monitor
For more information visit <http://www.lctu.org.uk/aboutus/jobs.asp>

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 Website & Email

Website. www.lctu.org.uk

Email lctu@liv.ac.uk



LCTU ADDRESS AND LOCATION



LCTU Address & Tel No

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