

LCTU NEWSLETTER

Cancer Research UK Liverpool Cancer Trials Unit



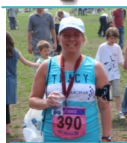
MERRY CHRISTMAS





Christmas Randomisation Cover

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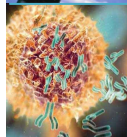
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LCTU Christmas Randomisation Cover

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

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

1st - 3rd January: No randomisations - LCTU closed



	29/12/2008	30/12/2008	31/12/2008
HOPON	No randomisations	Ring coordinator on +44 (0) 151 794 8934 if you would like to recruit or if you wish to report a SAE.	No randomisations
ITEM	No recruitment	Ring coordinator on +44 (0) 151 794 8934 if you would like to recruit or if you wish to report a SAE.	No recruitment
ESPAC-4	No randomisations	Ring Rob Hanson for randomisations. SAEs will also be picked up. Tel. +44 (0) 151 794 8935.	No randomisations
TELOVAC	No randomisations	Ring Jo Eatock for randomisations. SAEs will also be picked up. Tel. +44 (0) 151 794 8898.	No randomisations
PACIFICO	No randomisations	Ring James Dodd for randomisations. SAEs will also be picked up. Tel. +44 (0) 151 794 8897.	No randomisations

Fundraising



Cancer Research UK fund pioneering research so we are very keen to get involved and help out wherever we can.

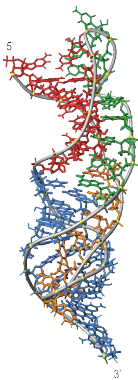
The 2010 events are now being arranged. If you would like to take part in a Race for Life event please register your interest at www.RaceForLife.org.



TeloVac Update

The TeloVac trial has continued to go from strength to strength this year. The 555th patient, the halfway point, was reached in October and as we approach Christmas we are close to reaching 600 patients randomised to the trial which is a remarkable achievement. We now have 52 sites open and recruiting to the trial and it is the efforts of all these sites that have helped us achieve our amazing recruitment figures.

The TeloVac Translational Sub-Studies for Immunomonitoring and Future Analysis have also proved very successful this year. 13 sites are currently participating in the translational studies and are now providing samples on a regular basis. With a further 7 sites currently in set-up, we hope that the translational studies will continue to be successful in the new year. We are extremely keen for more sites to participate in these sub-studies and would like to encourage any sites who are interested to contact the unit for further details.

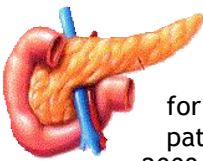


The TeloVac team has also had a few changes this year. Gemma Padgett has taken over the Trial Co-ordination and Joanne Eatock is now the Senior Trial Monitor. The monitor team has also been joined by Chris Hands and Gemma Simpson and the team are continuing to visit sites on a regular basis. Alan English, Hayley Jelleyman, Tony Coffey and Elisa Salvi are all continuing to provide sites with support from their roles as TeloVac Data Managers at the LCTU.

Once again, we would like to thank all those participating in the TeloVac trial for their continued hard work and commitment towards making the trial a success.

If you require any further information regarding the TeloVac trial please contact the Trial Coordinator, Gemma Padgett (contact details on back page) or visit the LCTU website www.lctu.org.uk.

ESPAC-4 Update



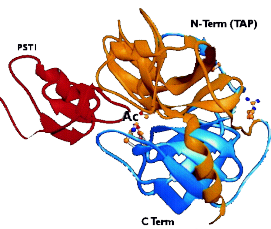
ESPAC-4 opened to recruitment at both the Royal Liverpool and Broadgreen University Hospital and Clatterbridge Centre for Oncology in October 2008 and the first patient was randomised on 10th November 2008. We now have a total of 27 sites open (20 in England and 7 in Sweden, led by Professor Lind) with many more planned across the UK and Sweden. Research Site Agreements continue to be sent out to UK sites and sponsorship contract negotiations are well underway with our counterparts in Germany and France. We have recently recruited the 51st patient to the trial.

ESPAC is an international collaboration and we are aiming to promote the study across Europe and the rest of the world. We are hoping to open centres in France, Finland and Germany in the new year. We are also in talks with collaborators in Italy, Greece, Austria, India, Hungary and the Netherlands to try and launch ESPAC-4 in these countries.

Site	Pats.	Also open but not yet recruited are:
Royal Liverpool Uni. Hospital	4	the Royal
Royal Surrey County Hospital	4	Marsden Hospital,
The Christie	8	Yeovil District Hospital,
St. James's, Leeds	2	Norfolk and Norwich
Ipswich Hospital	1	University Hospital, Ad-
Clatterbridge Ctr for Oncology	10	denbrooke's Hospital,
Guy's and St. Thomas's	1	Salisbury District Hospi-
Bristol Oncology Centre	2	tal, Poole Hospital, Bas-
Weston Park Hospital	6	ingstoke & North Hamp-
Walsgrave Hospital	1	shire Hospital, North
Derriford Hospital	2	Devon District Hospital
Karolinska University Hospital	4	and Royal Bournemouth
Eskilstuna	2	General Hospital in the
Malmo	2	UK and Lund and
Umea University Hospital	1	Vasteras in Sweden.
Uppsala University Hospital	1	

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.

EUROPAC2



EUROPAC2 is a multi-centre, double blind, randomised controlled trial to investigate the efficacy of ANTOX (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 and 65 years old that have been diagnosed with HP or ICP. We have currently recruited 14 patients within the UK and the total recruitment for the study is 84. The LCTU will be opening more centres within

the UK during the new year - if your hospital is interested in taking part in the trial please contact the trials unit for more information.

Sarah Jones has recently been appointed as the Trial Coordinator for this study; please contact her for more information (contact details on back page) or visit the LCTU website www.lctu.org.uk.

Open trials - Phase III (continued)

PACIFICO

*PACIFICO is a 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 anthracyclines considered inappropriate). Target recruitment is 680 patients in total, with 340 in each arm.

91 sites from across the UK have already expressed an interest in PACIFICO, 2 of which are now open, with a further 79 in set-up. We hope to open several more sites by early 2010.

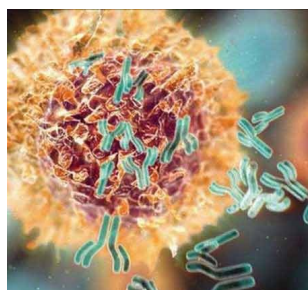


Image shows Rituximab binding to a cell surface

The first PACIFICO site (Royal Liverpool and Broadgreen University Hospital) was opened to recruitment in September 2009, and the first patient was recruited in October. A second site (Mount Vernon Hospital) has been opened in December 2009.

If you would like more information or would like to take part in PACIFICO trial, please contact the trial coordinator Stacey Carruthers (contact details on back page) or visit the LCTU website www.lctu.org.uk.

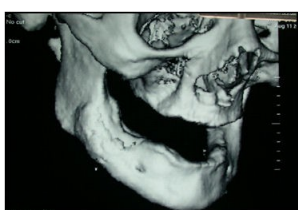
**Purine-Alkylator Combination In Follicular lymphoma Immuno-Chemotherapy for Older patient: a phase III comparison of first-line R-CVP versus R-FC*

Open 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. Since opening in September 2008, 36 patients have been recruited out of the target 50 patients.

The following centres are recruiting to the trial: Royal Liverpool University Hospital and University Hospital Aintree, Leeds Teaching Hospitals NHS Trust, St Luke's Hospital, University Hospital Birmingham, Guy's Hospital, St Bartholomew's Hospital, Glan Clwyd Hospital, Aberdeen Royal Infirmary, Derriford Hospital, Musgrove Park Hospital & Yeovil District Hospital, Manchester Royal Infirmary and North Manchester General Hospital.

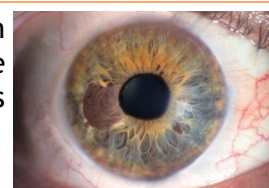


The following sites are expected to open to recruitment in the near future: Royal Devon and Exeter, St Bartholomew's Hospital and Guy's Hospital. Internationally, the Royal Brisbane and Women's Hospital in Australia, Antoni van Leeuwenhoek Hospital in Amsterdam and Copenhagen University Hospital in Denmark are also in the process of joining the trial.

A CTAAC application will be submitted before the end of the year to expand this feasibility study to phase III. 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 24 patients have been recruited out of the target of 25 patients with another patient lined up to be the last recruit. The Final Analysis will be conducted in 2010. For more information contact the Trial Co-ordinator Matthew Bickerstaff (details on back page) or visit the LCTU website www.lctu.org.uk.

SUAVE

Suave is a randomised phase II study of Sunitinib versus Dacarbazine in the treatment of patients with metastatic uveal melanoma. This trial aims to recruit 124 patients across approximately 10 sites in the UK. The LCTU plans to open this study to recruitment in the new year.

Please contact the Trial Coordinator Sarah Jones for further information (contact details on back page) or visit the LCTU website www.lctu.org.uk.

PET-Panc

Full title: the impact of combined modality positron emission tomography with computerised tomography scanning (PET/CT) in the diagnosis and management of pancreatic cancer.

This multicentre, HTA-funded UK study will determine the incremental diagnostic accuracy and impact of PET/CT in addition to standard diagnostic workup in patients with suspected pancreatic cancer.

A maximum of 600 patients will be recruited in the UK.

The study will be submitted for ethical approval in January.

For more information please contact Charlotte Rawcliffe (details on back page) or visit the LCTU website www.lctu.org.uk.



A typical PET facility

INPIC

INPIC proposes to use consensus methodology to clarify the role of cordotomy in the management of mesothelioma-related pain.

The study will examine whether there is sufficient evidence to support continued provision and commissioning of cordotomy and aim to provide a benchmark for the availability and use of this procedure in the treatment of pain associated with mesothelioma in the U.K. Following this it is proposed to establish a national registry study for cordotomy in mesothelioma-related pain management.

The study has been submitted for ethical approval and a decision is expected imminently. We will be using the internet as the main method of data capture and the website has now been developed and tested. We are hoping to recruit clinicians to participate early in 2010.

For more information please contact the Trial Coordinator Gary Jeffers (details on back page) or visit the LCTU website www.lctu.org.uk.

Expansion of the LCTU

The Liverpool Cancer Trials Unit has been established for 13 years and has experience and expertise in running pancreatic cancer trials, in particular, but has recently expanded its portfolio to include trials in such specialities as melanoma, head and neck and haematology.

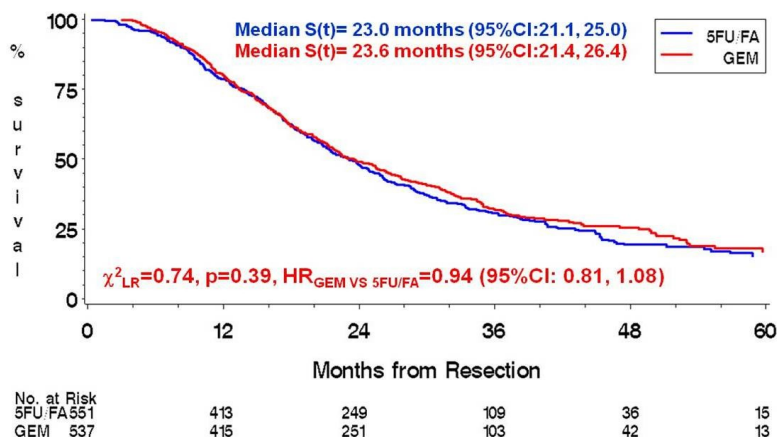
The LCTU will soon benefit by receiving additional core investment stemming from the achievement of the University of Liverpool, the Royal Liverpool University Hospital, Clatterbridge Centre for Oncology NHS Foundation Trust, Liverpool City Council and Cheshire Cancer Task Force in collectively obtaining Cancer Research UK Centre status.

We are in discussions with several researchers to open a further 10 trials in a range of specialities on top of the five phase III and three phase II trials already running. For more information regarding the possibility of the LCTU running your study please contact the Operational Director, Dr Seema Chauhan, for an informal discussion in the first instance; following this we will be able to take the trial forward in the most appropriate way. Seema can be contacted by telephone, +44 (0)151 794 8938, or by email, chauhans@liverpool.ac.uk. A trial adoption proforma can be downloaded from here: www.lctu.org.uk/aboutus/trialadoption.asp.

ESPAC-3(v2)

ESPAC-3(v2) opened in July 2000 and recruited 1583 patients in 159 centres across 17 countries and is the largest adjuvant trial ever conducted for pancreatic ductal adenocarcinoma. All trial treatment is now completed and all patients are in follow-up. The final two year survival analysis of the ductal patient was presented at ASCO 2009 and showed no significant difference in survival between adjuvant 5FU/FA and adjuvant GEM. We hope to have the results including the global Quality of Life data submitted for publication early in the New Year.

The Ampullary patients will all reach at minimum of 2 years follow-up in the May 2010 and the time of the analysis will depend on when the required event rate is met (minimum 50 in each group). We continue to focus on collecting follow-up and Quality of Life data. Many thanks to everyone working on the study for their help with the data collection effort.



Translational and Liverpool ECMC

Liverpool Experimental Cancer Medicine Centre

Emily Owen has recently taken over as the Liverpool ECMC Coordinator (contact details on back page).

Liverpool (comprising of the University of Liverpool School of Cancer Studies and Pharmacology, the Royal Liverpool University Hospital and Clatterbridge Centre for Oncology) is one of 19 sites across the UK which is part of a network of Experimental Cancer Medicine Centres (ECMCs) that have been established to drive the development of biomarkers and new anti-cancer treatments.



Biobanking is a major component of LECMC activity. To date, 5347 samples have been collected from 2103 patients. Purpose-built Good Clinical Laboratory Practice (GCLP) facilities within LECMC are fully equipped for sample reception, logging, processing (including cell separation from blood), assay and storage. A pharmaceutical monitoring system (Pharmagraph) monitors the temperature (freezers and incubators) and a Laboratory Information Management System (LIMS) tracks all samples that are stored and processed in the GCLP

facility. In addition, the GCLP laboratories have specialist equipment for rapid, automated, high throughput DNA extraction and for specific assays, including a Fluorescence-activated cell sorter (FACS) and ABI Triple Quad 5500 mass spectrometer.



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.

We now have approval for 37 UK sites and have received samples from Royal Liverpool University Hospital, and 26 other hospitals to date. We are currently requesting samples from other countries including Australia.

We would like to thank Queen Elizabeth Hospital, Birmingham for their co-operation during our recent visit to identify samples.

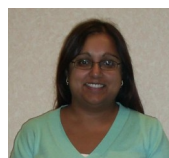
The table on the right shows a breakdown by country of samples received.

If any sites are in need of help to retrieve samples please let us know and we will arrange a time to visit. A new Trial Coordinator will soon be appointed but in the meantime Charlotte Rawcliffe (details on the back page) can be contacted if you have any queries.

Country	Paraffin Embedded	Frozen	Blood
UK	431	59	33
Germany	61	50	
Greece	34		
Italy	99		
Canada	31		
Finland	2		2
Total	658	109	35

Staff Update

Since our last newsletter we have several new additions to the LCTU team. Dr Seema Chauhan has been appointed as the Operational Director of the LCTU, taking over from Julia West. Seema previously worked as the Clinical Research Officer for the School of Cancer Studies.



*Seema Chauhan
(Operational Director)*

We welcome Sarah Jones as the Trial Coordinator for EUROPAC2 and the forthcoming uveal melanoma trial, SUAVE. Chris Hands and Gemma Simpson have joined as Trial Monitors for TeloVac. Emily Owen has returned to take over the coordination of the LECMC and will work with Seema to develop new trial applications.



*Sarah Jones
(EUROPAC2 and
SUAVE Coordinator)*



*Gemma Simpson
(TeloVac Monitor)*

We bid farewell to Tracy Ball who began a trial coordination post at the MCRN in November and also to Rosie Davies from the LECMC. We wish them both the best of luck!



*Chris Hands
(TeloVac Monitor)*

Many thanks to Virginia Kellond for all her help updating the EUROPAC2 database.

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 past 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. With Liverpool's new status as a Cancer Research UK Centre we will be able to enhance the delivery of high quality research.
- ◆ 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)
Operational Director - Seema Chauhan (chauhans@liverpool.ac.uk)
Lecturer in Medical Statistics - Susanna Dodd (s.r.dodd@liverpool.ac.uk)

SUAVE and EUROPAC2 Coordinator—Sarah Jones (s.c.jones@liverpool.ac.uk)
EUROPAC Research Fellow - Jane Butler (j.v.butler@liverpool.ac.uk)
EUROPAC Database Manager - TBA

TeloVac Coordinator - Gemma Padgett (g.a.padgett@liverpool.ac.uk)
TeloVac Monitor - Joanne Eatock (j.eatock@liverpool.ac.uk)
TeloVac Monitor - Chris Hands (cjdhands@liverpool.ac.uk)
TeloVac Monitor - Gemma Simpson (g.simpson@liverpool.ac.uk)
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TeloVac Data Manager - Alan English (a.j.english@liverpool.ac.uk)
TeloVac Data Manager - Elisa Salvi (elisa.salvi@liverpool.ac.uk)
TeloVac Data Manager - Anthony Coffey (tony.coffey@liverpool.ac.uk)

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

ITEM and HOPON Coordinator—Matthew Bickerstaff (oasis@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)

INPIC Coordinator and ESPAC-3(v2) Data Manager - Gary Jeffers (gary.jeffers@liverpool.ac.uk)

Liverpool ECMC Senior Coordinator - Emily Owen (eowen@liverpool.ac.uk)
Liverpool ECMC Research Nurse (CCO) - Jan Davies (janet.davies@liverpool.ac.uk)
Liverpool ECMC Research Nurse (RLUH) - TBA
Liverpool ECMC Laboratory technician - Katie Bullock (katie.bullock@liverpool.ac.uk)

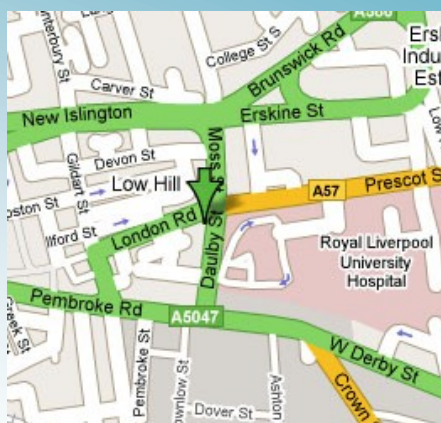
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