

# NEWSLETTER

Welcome to the fourth edition of the Liverpool Cancer Trials Unit Newsletter. Sorry for the lateness of this edition of the newsletter but due to a quiet summer we decided to do a later update.

## LCTU opens three new CRUK trials

### ESPAC-4 (CTAAC Funding)

ESPAC-4 is a two arm open-label, phase III, multi-centre international randomised control trial. The aim of this trial is to compare survival following resection and either adjuvant gemcitabine plus capecitabine or gemcitabine alone in patients with pancreatic ductal adenocarcinoma. The trial will be coordinated from the LCTU by Emily Owen (currently the ESPAC-3(v2) coordinator). The Chief Investigator of the trial is Professor Neoptolemos with Professor David Cunningham as the Trial Oncologist (pictured here on the right). The trial will recruit 1080 patients from approximately 160 centres in 18 different countries. These patients will be randomised into one of two arms—Gemcitabine alone or Gemcitabine with Capecitabine. Patients will then be followed up every three months from randomisation until death. The trial aims to begin recruiting early 2008.



### HOPON (FSC Funding)

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

Patients who have received radiotherapy to their jaws during treatment for head and neck cancer are at risk of a condition called osteoradionecrosis, often requiring complex and prolonged treatment. This study measures the value of high pressure oxygen therapy in reducing this risk.



The Chief Investigator of the trial will be Mr Richard Shaw (picture on the left) (Story continues on page 2)

### ITEM (FSC Funding)

Item is a single arm phase II study of Imatinib in good performance status patients with C-Kit positive metastatic Uveal Melanoma.

Metastatic eye melanoma carries a dismal prognosis, and to date, no systemic or regional therapy has shown a survival advantage over best supportive care. The study aims to determine potential clinical efficacy of Imatinib therapy using conventional imaging and RECIST criteria for response.

The Chief Investigator will be Dr Ernie Marshall.

(Story continues on page 2)



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#### IMPORTANT NOTICES

**Emily Owen the trial coordinator of ESPAC-3(v2) would just like to inform everyone that the ampullary arm of the ESPAC-3(v2) trial is still recruiting. There are 21 patients left to be recruited before the trial closes.**

Sadly since our June newsletter we have bid farewell to two members of staff. Alison Bates has started an exciting new job in London while Phillippa Davey has returned to university. However we would like to welcome our new TeloVac monitor Joanne Eatock



## HOPON (cont)

This study is run jointly between University Hospital Aintree & University of Liverpool. The study is aiming to start at the beginning of December and plans to recruit around 80 patients.

### Background

The case for the benefit of hyperbaric oxygen (HBO) in the prevention of osteoradionecrosis (ORN) was initially made by a small randomised controlled trial over 20 years ago. Some UK units adopted the use of HBO for at risk procedures such as dental extraction and implant placement, however others did not.

### Relevance

Treatment paradigms for head and neck cancer show a trend towards organ preservation and hence the use of radiotherapy is now very common. The dentition often deteriorates following radiotherapy and extractions frequently become necessary.

### Aims

To determine the benefit of HBO in the prevention of ORN at the time of a surgical procedure to the "at risk" irradiated mandible.

Patients will be randomised to 2 arms: HBO as standard protocol and best care without HBO

The trial will be initially coordinated by Emily Owen

## ITEM (cont)

The two year study will be run by Clatterbridge Centre for Oncology and aims to open at the beginning of December of this year. The study aims to recruit 32 patients between four sites.

### Background

Uveal melanoma represents a rare cancer with an incidence of 6 per million with biology distinct from cutaneous melanoma. Median survival varies from 2 to 6 months and conventional chemotherapy yields a response rate of  $\leq 10\%$ . The addition of Imatinib to uveal melanoma cell lines expressing c-kit inhibits cell proliferation, reduces transformation and induces apoptosis. No clinical studies of Imatinib in uveal melanoma have been published; however, anecdotal clinical responses were reported in 2 patients with advanced c-kit expressing uveal melanoma who received Imatinib.

### Relevance to Cancer

Uveal melanoma remains an orphan disease with few published trials.

### Specific Aims

To determine the efficacy of Imatinib in patients with metastatic uveal melanoma in terms of response rate with secondary endpoints of progression free survival, overall survival, safety and toxicity.

The trial will be initially coordinated by Julia West

## LCTU Out and About

This month the newsletter includes some news and pictures from when the LCTU attended various conferences around the UK. Since June the LCTU has been to three events; in July there was the European Pancreatic Club Meeting in Newcastle and the National Cancer Research Institute Upper GI conference in London; and just recently we attended the National Cancer Research Institute Annual Conference in Birmingham. We have many pictures from these events as well as news, stories and updates.



Emily Owen the trial coordinator for ESPAC-3 (v2) presents the latest trial figures at the European Pancreatic Club Meeting in Newcastle



Gemma Welsh, Michelle Mossa, Julia West and Emily Owen by the LCTU stand at the EPC meeting in Newcastle.



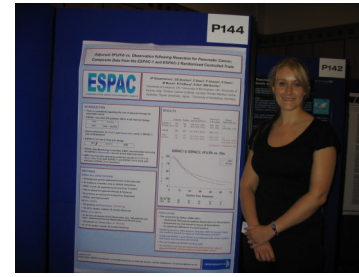
Professor J Neoptolemos at the EPC. Professor Neoptolemos gave a talk about ESPAC-4 as well as participating in a debate about 5FU versus Gemcitabine



The LCTU stand at the NCRI Conference in Birmingham.



Dr Bill Greenhalf at the EPC. Bill talked about the ESPAC-Tplus trial as well as introducing Tracy Ball as the new Espac-T support officer.



Emily Owen the trial coordinator for the ESPAC-3(v2) trial gave a talk about her trial.

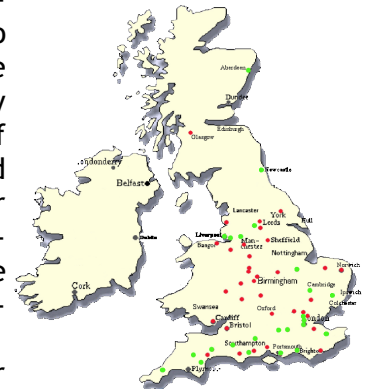
## TeloVac Update and Latest News



The TeloVac Trial is in its eighth month of recruitment, it now has over 50 patients in the trial and recruitment is rapidly increasing. There are 29 centres now open with more to get the green light within the next few weeks, a full list of participating sites can be found on the LCTU web-site below. Top marks to The Royal Surrey Hospital for recruiting 13 patients in 8 months and we look forward to the rest of the centres continuing with the success they have demonstrated so far. The LCTU are delighted with the progress of the study and would like to extend a massive thank you for all the hard work, professionalism and dedication that has brought the study this far by the participating sites. The DMC will be held in October and any outcomes will be reported by the Trial Steering Committee shortly after. The monitoring staff have commenced their activities with 4 sites already visited and more to come soon, go easy on them - they mean well!



As ever, feel free to contact the TeloVac team at any time for more information at [www.lctu.org.uk](http://www.lctu.org.uk)



Latest map showing open sites

## ESPA3-3(v2) Trial Update

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



There are now 21 Ampullary patients still required to be randomised to reach the target figure of 300 patients. Data collection continues in anticipation of an interim analysis early next year. If you have any outstanding data please send it in asap.

## ESPA3-Tplus Trial Update

We have now established the ESPA3-Tplus database which allows us to recode samples in order to comply with national regulations. The MREC application has been approved by the Liverpool (Adult) Research Ethics Committee. The first committee meeting will be held early 2008, to be chaired by Professor Nick Lemoine, and consist of translational scientists. ESPA3-Tplus will also have its own Newsletter—if you would like to receive this newsletter please contact Tracy Ball (contact details on back page)



Tracy would like to say “Thank you to the sites who have already shown an interest in the study”

## EUROPAC2 Trial Update

EUROPAC2 has now randomised seven patients at the Royal Liverpool and Broadgreen University Hospital taking the total recruited across Europe to 53. The trial is aiming to recruit a total of 240 patients between the two coordinating centres.

Southampton General hospital, Newcastle Freeman hospital and University College London hospital are in the process of obtaining R&D and ethics approval. Hopefully all these centres will be open to recruitment by the end of the year.



## GemCap Trial Update

The GemCap trial is now being managed by Gemma Welsh. If you have enquiries please contact Gemma via email at [gemma.welsh@liv.ac.uk](mailto:gemma.welsh@liv.ac.uk). Site closeout visits are currently taking place and are expected to be completed by the end of this year. Gemma would like to thank all the sites taking part for their continued cooperation.

## LECMC - Update and Latest News

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 LECMC has recently appointed Gemma Welsh as coordinator and is currently recruiting two research practitioners and a laboratory technician. Since opening, the Liverpool Experimental Cancer Medicines Centre has adopted 29 trials, two of these HOPON and ITEM will be coordinated through the LCTU

This is a new initiative in which we are developing collaborative links with our NHS trust partners. This is an exciting opportunity to move cancer research from research studies at a bench level to research in a clinical environment.





## LCTU STAFF AND CONTACT INFORMATION

### Contact Information

Unit Manager— Michelle Mossa (m.c.mossa@liverpool.ac.uk)

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Please visit the LCTU website ([www.lctu.org.uk](http://www.lctu.org.uk)) for more job vacancies

### 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](mailto:lctu@liverpool.ac.uk)

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

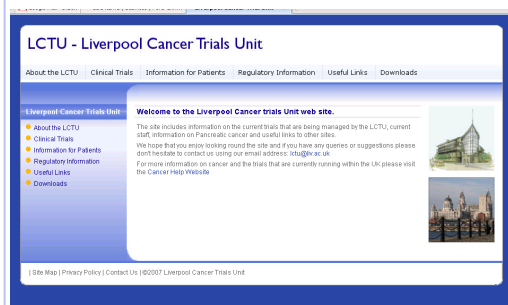
## Liverpool Cancer Trials Unit Vision

- ◆ 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](http://www.lctu.org.uk)

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