

NEWSLETTER

WELCOME MESSAGE

Welcome to the second edition of the Liverpool Cancer Trials Unit Newsletter. We hope to be able to send out newsletters every three months to keep everyone up to date on what is happening at the LCTU.

TeloVac Trial Now Open

Spring Heralds TeloVac Opening

This edition focuses on the opening of the TeloVac trial a phase III trial comparing combination Gemcitabine and Capecitabine therapy with concurrent and sequential chemoimmunotherapy using a telomerase vaccine in locally advanced and metastatic pancreatic cancer. All regulatory aspects of the trial were finally approved and official opening took place on March 5th.

There are now three sites that have completed the green light process: the Royal Liverpool and Broadgreen University Hospital, Clatterbridge Centre for Oncology and Royal Surrey Hospital. There are several more sites that are nearly ready to recruit including Christie Hospital and Addenbrookes Hospital. The first patient was randomised on 29th March.

For more information on sites that are taking part please visit our website www.lctu.org.uk



"We believe the future treatment of pancreatic cancer, as well as many other cancers, will include combinations of various chemotherapies together with biological and targeted therapies. GV1001 is a particularly attractive vaccine; the antigen that it targets is expressed on virtually all pancreatic cancer cells and the vaccine stimulates the production of all of the cells that are required for an effective immune attack upon these cancers. Adding it to the platform of chemotherapy is an exciting strategy which, if successful, would create a new standard of care in this disease." Dr. Gary Middleton (Chief Investigator)

"Despite the trial only recently opening to recruitment, we have already seen a lot of interest from patients' who are keen to explore newer treatment options over standard chemotherapy. Family and friends are retrieving information from the internet and are very positive about the prospect of this new treatment for pancreatic cancer" Cathy Whittemore (Research Practitioner)



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"The priority of the LCTU is to protect the rights, safety and well being of all cancer patients"

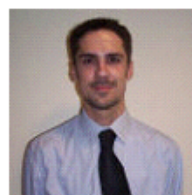
IMPORTANT NOTICES

We have now received feedback from the MHRA report with several findings. We would just like to reiterate to sites that no personal patient information should be sent or faxed to the LCTU.

FURTHER LCTU TRIALS

Watch this space for information on new trials starting within the LCTU including the new ESPAC-4 trial which will follow on from the completion of the ESPAC-3 trial.

Since our last issue we have lost a member of a staff but gained a new member. Sad farewells go to Steve Still who has returned to his post at Clatterbridge Hospital. He will be greatly missed. However we welcome Matthew Bickerstaff (shown here on the right) who is the new Data Manager for the Espac-3 (v2) trial



TeloVac Trial Update and Latest News

Update on TeloVac progress

The TeloVac trial officially opened on the 5th of March. A press release for the trial was released to the local area on the 26th of March; this was presented in the Echo and the Daily Post. The press release can be found at http://www.liv.ac.uk/newsroom/press_releases/2007/03/telovac.htm



Presently, approximately 65 sites have expressed interest in joining the TeloVac trial which is run from The Liverpool Cancer Trials Unit and the Trial Coordinator is Julia West. The TeloVac Senior Monitor, Carl Henry, has initiated nine of these sites with a target of six others to initiate over the next month. The LCTU is looking to recruit a further three monitors for TeloVac to cover all the sites

Three sites have the “Green light” for the TeloVac trial, Clatterbridge Centre for Oncology, Royal Liverpool and Broadgreen University Hospital and Royal Surrey Hospital, enabling them to start recruiting patients. As of yesterday the total trial recruitment was one patient, recruited by Royal Surrey Hospital

Any investigators wishing to join the trial or for general information, contact the TeloVac team at www.lctu.org.uk

TeloVac Trial In The Press

Liverpool to trial new pancreatic cancer therapy

(Taken from Liverpool University website)

Patients in Liverpool are to trial a new therapy for pancreatic cancer - a disease which sees most sufferers die within a year of diagnosis.

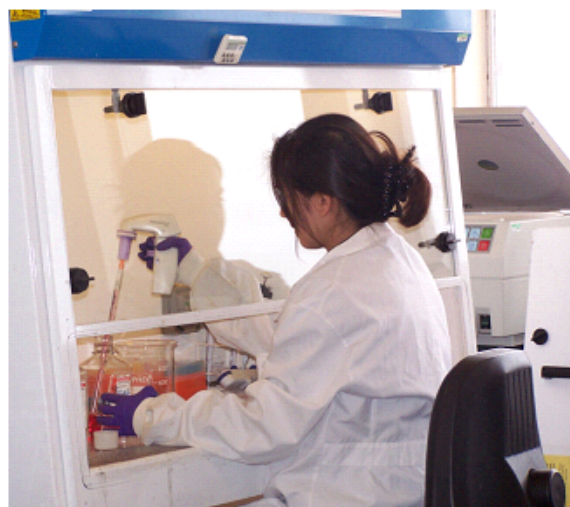
One of the 10 most common cancers in the UK, it is among the most difficult to diagnose and treat and kills around 7,000 people each year. There are very few early symptoms so most patients present late and only around 15% are suitable for surgery.

The Phase III TeloVac trial has been designed by the Pancreatic Cancer Clinical Sub-Group of the UK National Cancer Research Institute and will be run by Cancer Research UK's Liverpool Cancer Trials Unit.

Funded by Cancer Research UK, the trial will test the vaccine GV1001 alongside two chemotherapy drugs gemcitabine and capecitabine on patients with locally advanced and metastatic pancreatic cancer. GV1001 is a new immunotherapeutic drug for pancreatic cancer developed by Danish-based biotech company Pharmexa

Patients with non-resectable pancreatic cancer will be randomly distributed into one of three arms of the trial:

- 370 patients will be treated with gemcitabine and capecitabine in a standard treatment
- 370 patients will be treated first with gemcitabine and capecitabine for eight weeks, following which



they will be treated with GV1001

- 370 patients will be treated with gemcitabine and capecitabine and with GV1001 at the same time

The research team aims to find whether the patients treated with a combination of GV1001 and chemotherapy live longer than patients who only receive chemotherapy. It is not expected that GV1001 will cure patients, but that treatment will prolong their lives and that a small proportion of the patients may experience significantly longer survival.

The Liverpool Cancer Trials Unit is seeking to encourage centres throughout the UK to participate.

Trial Updates

ESPA3 Trial Update

ESPA3(v2) has now recruited 1522 patients. The target of 1030 patients with Ductal adenocarcinoma was reached last year. There are about 40 patients with Ampullary + other tumour types still to be recruited.



Many patients have been involved with this trial and it is not often we get to hear their stories. The following is an extract from an ESPA3 patient's story.

"My surgeon wanted me on the Espac 3 trial, a trial based in Liverpool England and covering Europe, Australia and New Zealand,I did 6 months on Gemcitabine (Gemzar) One treatment a week for 3 weeks, then one week off....My last CT scan done on November 16th, 2004 was clear for my abdomen but as the scan had caught the bottom of my lungs a nodule was seen which was followed up by a full lung CT scan in Jan. 2005 but this proved to be okay too...I would go through all this again as I consider this to be the cure for pancreatic cancer at this time" (Barbara NZ 04/01/2006)

To read the rest of this story please visit: www.lctu.org.uk/lctu_trials/espac3.html and click on **patient story**

EUROPAC2 Update

EUROPAC2 is a multi-centre, randomised phase III, double blind, placebo controlled, parallel group, outpatient study in patients aged 5-65 with Hereditary Pancreatitis and Idiopathic Chronic Pancreatitis and Idiopathic Chronic Pancreatitis.



EUROPAC2 is due to open in the next few weeks with the first centre to open being the Royal Liverpool and Broadgreen University Hospital. It is anticipated that a further 8 centres will be opened across the UK in the following months. Updates of recruiting centres will be provided on the LCTU website (www.lctu.org.uk) along with any additional EUROPAC2 updates.



There have been various changes to the EUROPAC2 protocol including a change in patient age range from 5-40 years to 5-65 years (subject to approval).

If you require more information on this trial please contact the trial coordinator Gemma Welsh on the details above.

The EUROPAC2 team are very excited at the imminent opening of the trial.

GemCap Trial Update

The GemCap is closed to recruitment.

Data cleaning is underway in preparation for final analysis.



UK Clinical Trials Units

CR UK Trial Units

If you would like to know more about other cancer trials taking place within the UK please visit the other cancer research UK trials units websites.

- MRC CTU - www.ctu.mrc.ac.uk/
- Birmingham Clinical Trials Unit - www.bctu.bham.ac.uk
- Leeds Clinical Trial Research Unit - www.leeds.ac.uk/medicine/nyctr/ctu_contents.htm
- UCL MRC Clinical Trials Unit - www.ucl.ac.uk/clinical-trials/
- Southampton CTU - www.ctu.soton.ac.uk/

You are in: UCL Online > Clinical Trials

Clinical Trials Sponsored Jointly by UCL & UCLH

Click on Trial Name

Home	<p>UCLH/UCL Joint Sponsorship of Clinical Trials</p> <p>These pages are for investigators conducting single site trials sponsored jointly by UCL/UCLH. The information on this site may also be of use to all investigators conducting trials under the Clinical Trials regulations but the pages are not intended to cover the requirements for complex multi-centre trials.</p> <p>Here you will find the information, guidance, forms and policy documents you need to comply with the Medicines for Human Use (Clinical Trials) Regulations 2004, otherwise known as the EU clinical trials directive. Trials sponsored jointly by UCL/UCLH are administered jointly by the</p>	<p>Useful Links</p> <ul style="list-style-type: none">Medical Statistics UnitList of Current TrialsCalendar of Training CoursesUCL Research & DevelopmentUCL BiomedicineUCL Research For Patients
What's new		
Pressing a trial		
Conducting a trial		
Closing a trial		
Training		
Legal matters		
Download Forms		
Download Policies		
A-Z of sites		
Contact Us		
<p>University College London Research</p>		

LCTU STAFF AND CONTACT INFORMATION

Contact Information

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

Espac-3(v2) Coordinator—Emily Owen (e.owen@liverpool.ac.uk)
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TeloVac Coordinator—Julia West (Julia.west@liverpool.ac.uk)

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The LCTU staff are constantly striving to improve their knowledge and skills by attending regular training courses. Recent courses attended by staff include ICH-GCP training, Introduction to Cancer and Accrual Data for the NCRN. The following courses will be attended by staff in the near future; clinical trial directive, GCP monitoring and ICH GCP for experienced staff.

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

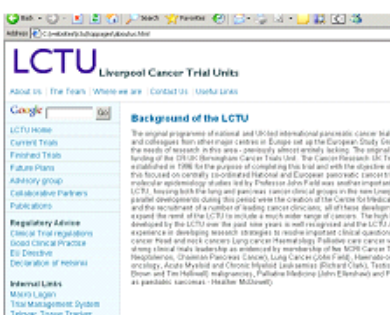
A patient liaison representative will be an independent advocate for patients.

Liverpool Cancer Trials Unit Vision

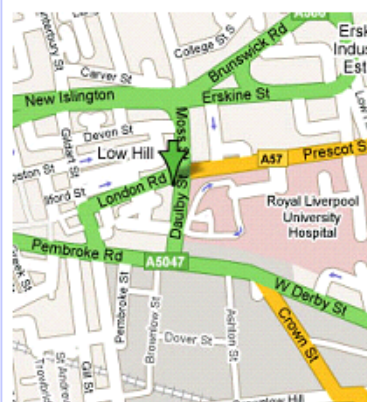
- ◆ The LCTU works closely with Cancer Research UK in the Clinical Research of new and existing products for the treatment of cancer, easing suffering and improving the quality of life of these patients.
- ◆ The LCTU is recognised for having a positive impact on peoples' lives, meeting the needs and 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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