

NEWSLETTER

WELCOME MESSAGE

Welcome to the third 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.

EUROPAC2 Trial Now Open

Another trial open at the LCTU

Another edition of the newsletter and another trial is open. The EUROPAC2 trial, a trial which is investigating the efficacy of ANTOX (Vers) 1.2 and MGCT (Magnesiocard ®) for the treatment of Hereditary Pancreatitis and Idiopathic Chronic Pancreatitis opened in the UK on the 8th May. The first site to open was the Royal Liverpool and Broadgreen University hospital. Currently this is the only site open however the Freemans hospital Newcastle and Southampton General Hospital will be the next sites to open.

More information on this trial can be found on page 2 or alternatively please visit the EUROPAC2 page on the LCTU website at <http://www.lctu.org.uk/trial/europac-2.html>



"We are very pleased that Liverpool has now opened as the randomisation centre for the UK and hope that other centres from the UK will contribute patients. We are proud to collaborate with our colleagues in Germany and elsewhere in Europe on what we hope will be a very valuable study."
Mr Michael Raraty UK Chief Investigator

"At long last we have the opportunity to test the widely held belief that anti-oxidants help to alleviate a lot of the pain and discomfort caused by pancreatitis, allowing us to put a popular treatment on a firm scientific foundation" Dr Bill Greenhalf, Senior Scientist at Liverpool



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

IMPORTANT NOTICES

Emily Owen the trial coordinator of ESPAC-3 would just like to inform everyone that the ampullary arm of the ESPAC-3 trial is still recruiting. There are 31 patients left to be recruited before the trial closes.

LCTU OUT AND ABOUT

The LCTU will be getting out of the office later this year at various clinical events. Members of the team will be present at both the EPC and NCRI Upper GI, and we will also be manning a stand at the NCRI annual conference in late October. Come along and find out more about what we do.

Since our last issue we have employed two new members of staff. We welcome Tracy Ball (shown here on the right) as the new Trial Support Officer and Joanne Eatock as a new Monitor. Joanne will be starting later this summer.



EUROPAC2 - Background to the trial

Approximately 18,000 patients in the UK currently suffer from chronic pancreatitis; a long-term inflammatory illness affecting the pancreas, which causes attacks of severe abdominal pain. It is becoming increasingly common and results in more than 5,000 hospital admissions each year. Unfortunately, no medical treatment has yet been proven to reduce the number or severity of attacks of pain in chronic pancreatitis, but there is some evidence to suggest that micronutrient antioxidants and/or magnesium may help.

The EUROPAC2 study is the largest study so far attempted on this topic. It is a multinational randomised controlled trial which aims to determine the efficacy of antioxidant medication (ANTOX) and magnesium (Magnesiocard) compared to placebo in the treatment of pain in patients with chronic pancreatitis using hereditary pancreatitis (HP) and idiopathic chronic pancreatitis (ICP) as models. Most patients will be recruited from the European Registry of Hereditary Pancreatitis and Familial Pancreatic Cancer (EUROPAC) which is coordinated from Liverpool and represents the worlds largest registry of patients with non-alcohol related pancreatitis.



We aim to recruit 240 patients in total between the ages of 5 and 65 years from 2 randomisation centres - Liverpool, UK and Griefswald, Germany. Patients will be randomised to receive ANTOX, magnesiocard or placebo. Quality of life and pain diaries will be completed by each patient over a one-year period.

Both treatment medications to be tested are relatively inexpensive but carry the potential to significantly reduce time lost from school or work for individual patients and also to reduce the number of admissions to hospital due to exacerbations of pain from chronic pancreatitis.

For more information on the EUROPAC2 trial please visit the LCTU website at www.lctu.org.uk/trial/europac-2.html

LECMC - Liverpool Experimental Cancer Medicine Centre

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 University Hospital and Clatterbridge Centre for Oncology and will be managed by the Liverpool Cancer Trials Unit.

The LECMC has developed the following multi-centre trials into its portfolio:

VEPEMB/SHIELD, CAMPRED/UKCLL06, CAM203, UKCLL201 (FGM±R), R-CODOX M/IVAC, R-GCVP, GEMCITABINE + BEXAROTENE, CLL207, BORTEZOMIB/CHOP, CAMFLUD/UKCLL02, HOPON, MetXia, KABI, TARGET, ITEM, BRCA, PRIME II, HIGH DOSE INTERFERON, TE23, EORTC 30983/TE21, EORTC 08062, NWCOG-3, BOXER, CA184-025 (COMMERCIAL), CA163-115 (COMMERCIAL), FUTURE (COMMERCIAL), TG4010 (MVA-MUC1) (COMMERCIAL), SCOPE1



New Staff and New Trial

Tracy Ball has recently taken up the post of ESPAC-Tplus Trial Support Officer. Her role will be to coordinate the transfer of tissue samples to the Liverpool Centre for every patient in the ESPAC trials. Tracy is currently contacting all ESPAC centres to find out availability of all materials.



The objective of ESPAC-Tplus is to identify markers in the primary tumour which predict improved probability of survival for either adjuvant 5-FU or Gemcitabine following resection for pancreatic ductal adenocarcinoma. The ESPAC-Tplus trial will centralise collection and characterization of tissue, which will then be coded and linked with clinical outcome data. Tissue microarrays and matched samples will be sent out to the ESPAC centres for direct analyses of proteins known to be related to 5FU and Gemcitabine resistance.



The project will ultimately enable specific treatments to be targeted to patients who are likely to respond with an improved survival. For more information on this trial please visit the website www.lctu.org.uk/trial/espact.html.

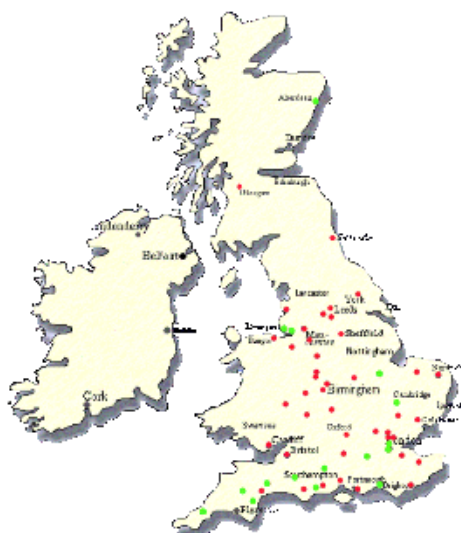
TeloVac Update and Latest News

TeloVac is a Cancer Research UK funded Phase III trial. 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

The trial officially opened on the 5th March and is now well under way with recruiting patients. So far 16 patients have been successfully recruited onto the trial.

The TeloVac team are pleased to announce that they have now given the green light to 16 sites. They would like to welcome on-board Aberdeen Royal Infirmary, Royal Marsden Hospital, Sussex Oncology Centre, Royal Bournemouth Hospital, Torbay District General Hospital, Southampton University Hospital, Huddersfield Royal Infirmary, Addenbrookes Hospital, Royal Cornwall Hospital, Peterborough General Hospital, Yeovil District Hospital in addition to Royal Surrey County Hospital, Clatterbridge Centre for Oncology and the Royal Liverpool Broadgreen University Hospital.

The trial which is run from the Liverpool Cancer Trials Unit has now had over 70 sites express interest, and with Carl Henry the Senior Trial Monitor travelling up and down the country, over 20 sites have now been initiated. We are now gathering final paperwork and are hoping to have more sites open over the next few months. The map on the right shows the locations of the open sites (in green) and the sites which have expressed interest (in red). This map can be seen in more detail at www.lctu.org.uk/trial/Telovac_sites.asp



If you are a recruiting centre on the TeloVac trial and you have any questions or queries please contact the Trial Coordinator Mrs Julia West or the Senior Trial Monitor Mr Carl Henry. Contact details can be found on the back page of the newsletter.

For more information on the trial please visit the TeloVac pages of the LCTU website at www.lctu.org.uk/trial/telovac.html.



ESPAC-3 Trial Update

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

Emily Owen the trial coordinator would like to thank everyone for all of their hard work and effort on the trial so far. There are now 31 Ampullary patients still required to be randomised to reach the target figure of 300 patients. Data collection continues in anticipation of an interim analysis later on in the year.

GemCap Trial Update

The GemCap trial is closed to recruitment. Data lock has now taken place and close out visits to sites are being arranged for late June early July.



LCTU Website Revamp

Earlier this month it became apparent that the LCTU website, despite only being a couple of months old was starting to look a little "tired" and "square". The original website was developed primarily as a source of information and to replace the old LCTU pages.

The new website was developed in house and is much more friendly on the eye. It is designed to make navigating around the LCTU site easy, by using expandable menus and clear links.

The site is constantly under development so please make sure you visit regularly.

www.lctu.org.uk



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)
EUROPAC2 Coordinator—Gemma Welsh (gwelsh@liverpool.ac.uk)
TeloVac Coordinator—Julia West (Julia.west@liverpool.ac.uk)

TeloVac Monitor—Carl Henry (c.henry@liverpool.ac.uk)
Database Developer — Laura Marsh (l.marsh@liverpool.ac.uk)

Data Manager—Alison Bates (Alison.bates@liverpool.ac.uk)
Data Manager—Phillipa Davey (phillipa.davey@liverpool.ac.uk)
Data Manager—Matthew Bickerstaff (oasis@liverpool.ac.uk)

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

Data Clerk—Wendy Scragg (Wendy.scragg@liverpool.ac.uk)
Data Clerk—Paul Thompson (Paul.thompson@liverpool.ac.uk)

Clinical Research Officer—Seema Chauhan (seema.chauhan@liverpool.ac.uk)
Research Practitioner—Catherine Whitmore (c.whitmore@liverpool.ac.uk)

Senior Statistician—Catrin Tudur-Smith (cat1@liverpool.ac.uk)
Trial Statistician—Susie Dodd (s.r.dodd@liverpool.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.

Liverpool Cancer Trials Unit Vision

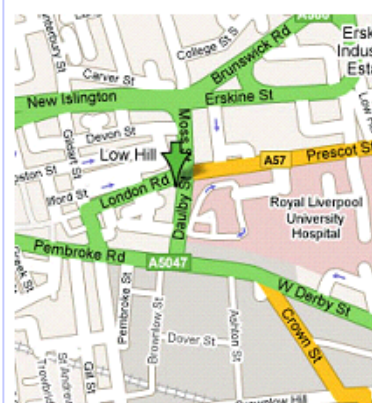
- ◆ The LCTU works closely with Cancer Research UK in the Clinical Research of new and existing products for the treatment of cancer, easing suffering and improving the quality of life of these patients.
- ◆ The LCTU is recognised for having a positive impact on peoples' lives, meeting the needs and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

Liverpool Cancer Trials Unit
Cancer Research Centre
200 London Road
Liverpool
L3 9TA

Tel. +44 (0) 151 794 - 8938/8937
Fax. +44 (0) 151 794 - 8930/8931