



MERRY CHRISTMAS FROM LIVERPOOL CANCER TRIALS UNIT

Welcome to the first edition of the LCTU newsletter.

This edition introduces the new staff as well as providing up to date information on the latest trials the LCTU is running

THANKS FROM THE LCTU

GemCap

Just a little message to say thank you to all the sites involved for the extra work contributed to the retrospective monitoring of GEMCAP. This is a very challenging but important part of the process. This data will be presented in a high impact academic journal and your continued commitment is very much appreciated. We understand this is very labour intensive but hopefully with your support this process will be over by the end of January.



Espac-3 (V2)

This is the highest recruiting international trial into adjuvant chemotherapy in pancreatic cancer in the world. Thank you to all the sites who have entered patients onto the Espac-3 trial. The trial has entered a staggering 1488 patients and has reached its target. This has been a wonderful effort by each of the participating sites and Emily would like to thank each of you personally.



TeloVac

Thanks to everyone involved in the TeloVac trial for all the interest and hard work you have put in so far. The study is in final stages of set-up and will be ready to recruit at the end of January 2007. The enthusiasm ALL have shown to take part in this challenging and potentially ground-breaking trial has been an inspiration. Enjoy the Christmas break and very best wishes.



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

IMPORTANT

The LCTU winter closing times: 1pm Friday 22nd December–9am Tuesday 2nd January. During this period the randomisation service will not be available. We apologise for any inconvenience caused.

LCTU TEAM

Top Row (L-R):
Carl Henry, Paula
Ghaneh, Laura Marsh,
Phillipa Davey,
Wendy Scragg,
Gemma Welsh

Bottom Row (L-R):
Paul Thompson,
Alison Bates, Emily
Owen, Steve Still,
Michelle Mossa



LATEST LCTU TRIAL INFORMATION

GemCap Study

ISRCTN: 11513444

Opened: July 2002

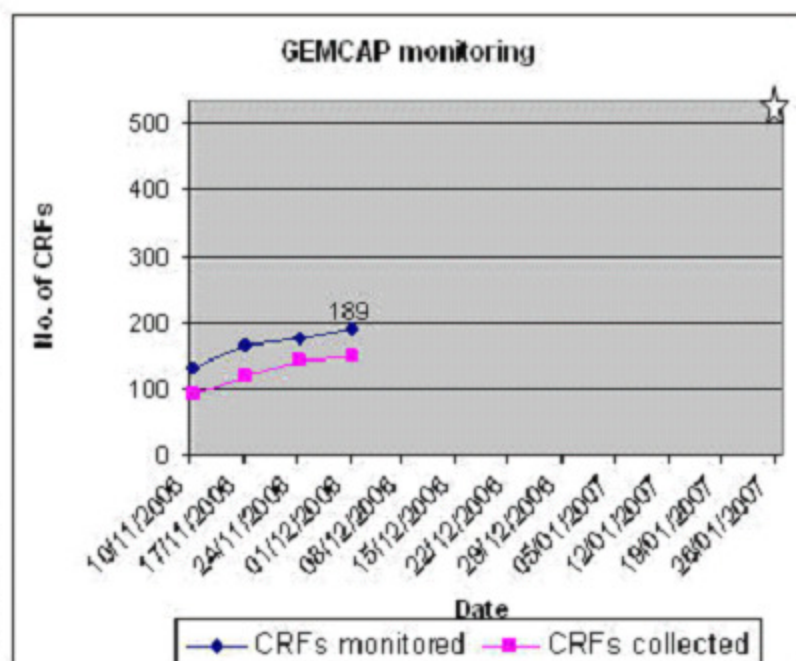
Closed to recruitment: Jan 2005

Patients recruited: 533

Trial Details

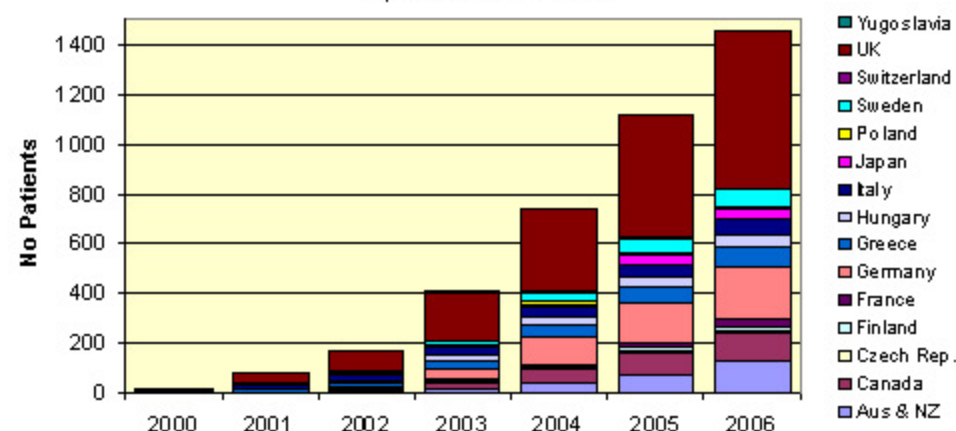
A phase III multi-centre randomised clinical trial comparing Gemcitabine alone or in combination with Capecitabine for the treatment of patients with advanced pancreatic cancer.

The GEMCAP trial has stopped recruiting and is in the process of retrospective monitoring. We're hoping to have complete data lock by the 26th of January 2007. The current state of the monitoring is 189 CRFs.



Espac-3 (v2) Study

Espac-3 Recruitment



Opened: July 2000

Ductal Closed to recruitment: Dec 2006

Ampullary: DMC make recommendations Jan '07

Patients recruited: 1493

Study Coordinator: Emily Owen

The ESPAC-3(v2) trial design evolved from the final analysis of the ESPAC-1 study, and is an Phase III clinical trial comparing 5FU and D-L Folinic Acid v Gemcitabine in resectable Pancreatic Cancer (Ductal). The Ampullary/other arm compares observation v Gemcitabine v 5FU and D-L Folinic Acid

Special Thanks from the Espac-3 Coordinator Emily Owen

"Thank you to Germany, Australia, New Zealand and Canada for being the highest recruiting international countries.

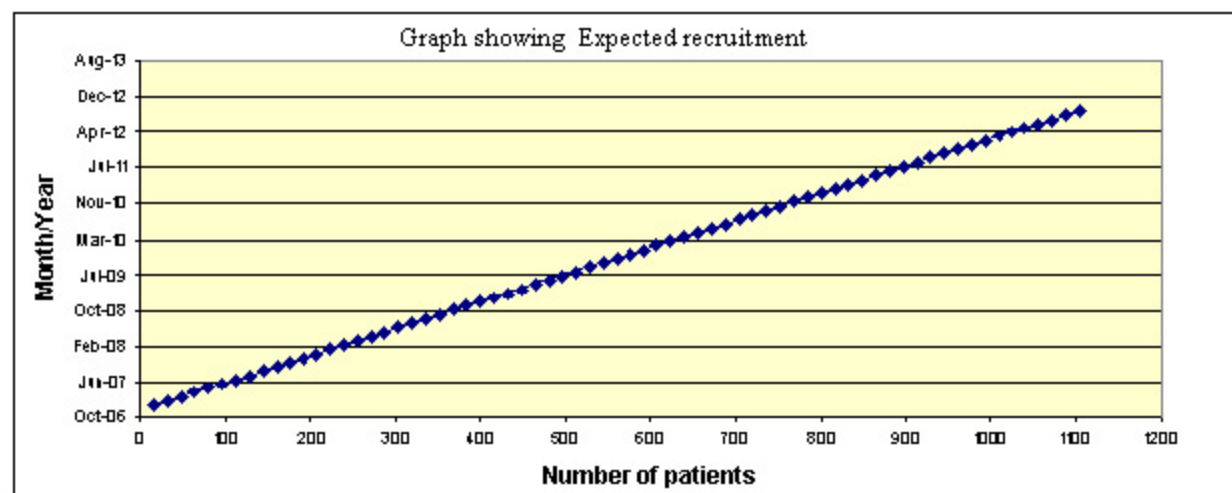
Thank you to the Christie Hospital, Manchester; Queen Elizabeth Hospital, Birmingham and the Addenbrookes hospital Cambridge for being the highest recruiting centres in the UK.

Also, a big thank you to all the other countries and sites who haven't taken part in the trial for their valuable contributions and in making this the highest recruiting international trial into adjuvant chemotherapy in pancreatic cancer in the world"

Centrally coordinated from the LCTU, this trial has recruited in excess of 1400 patients from more than 150 centres in 17 countries throughout Europe, Australia, Canada, Japan and New Zealand. Accruing more than 30 patients per month, ESPAC-3(v2) reached the target of 1030 patients with Ductal adenocarcinoma on 13th December 2006. Following recommendations from the IDSMC, patients with Ampullary + other tumour types will continue to be recruited until the next IDSMC meeting in January 2007.

LATEST LCTU TRIAL INFORMATION (Cont...)

TeloVac Study



ISRCTN: 43482138

Opened: due to open January 2007

Expected patient recruitment: 1110

Study Coordinator: Julia West

This study is designed as a prospective, phase III, controlled, open-label, multi-centre, randomised clinical trial comparing combination Gemcitabine and Capecitabine therapy with concurrent and sequential immunotherapy using the telomerase vaccine GV 1001 in locally advanced and metastatic pancreatic cancer.

Patients will be treated until disease progression and will be subject to follow-up until death.

1. Gemcitabine and Capecitabine.
2. Gemcitabine and Capecitabine then sequential GV1001 followed by further Gemcitabine for patients where no progressive disease (PD) was demonstrated upon the week 8 CT.
3. Concurrent administration of Gemcitabine and Capecitabine and GV1001.

Target recruitment is 1110 patients (370 within each arm).

The Capecitabine will be fully funded by Roche Pharmaceuticals and will be distributed free of charge. See BJC paper—for phase I/II full paper {ref: CTN 1-2000 BJC paper.pdf}.

Europac-2 Study

Due to open: January 2007

Expected Recruitment: 240 (across UK & Germany)

Trial Coordinator: Gemma Welsh

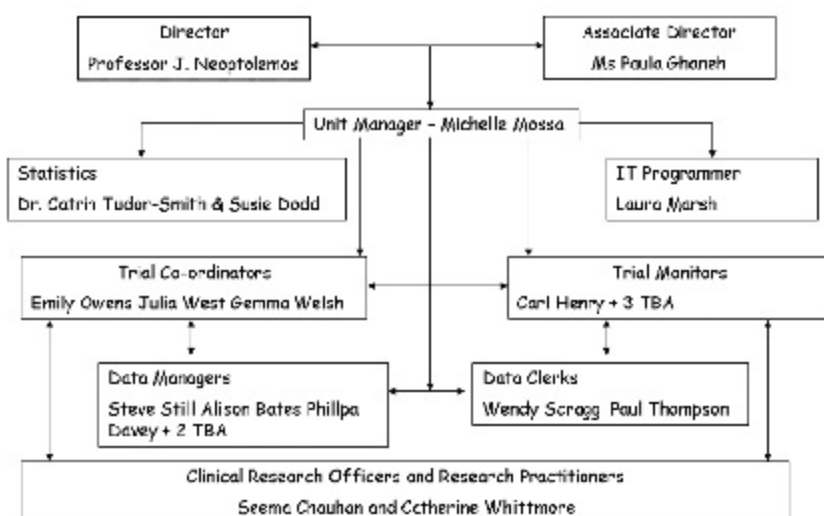
EUROPAC 2 is a multi-centre, randomised phase III, double blind, placebo controlled, parallel group, outpatient study in patients aged 5-40 with hereditary Pancreatitis and Idiopathic Chronic Pancreatitis and Idiopathic Chronic Pancreatitis.



MERRY CHRISTMAS FROM THE LCTU

LCTU STAFF AND CONTACT INFORMATION

LCTU Staff Structure



Contact Information

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

Espac-3(v2) Coordinator—Emily Owen(e.owen@liverpool.ac.uk)
 Europac-2 Coordinator—Gemma Welsh(gwelsh@liverpool.ac.uk)
 TeloVac Coordinator—Julia West (to be announced)

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

Data Manager—Stephen Still(stills@liverpool.ac.uk)
 Data Manager—Alison Bates (Alison.bates@liverpool.ac.uk)
 Data Manager—Phillipa Davey phillipa.davey@liverpool.ac.uk)

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

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 Research Practitioner—Catherine Whittmore—(TBC)

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

MANAGEMENT BOARD

Director of LCTU

Professor John Neoptolemos. Division of Surgery and Oncology, RLUH.

Associate Director of LCTU

Ms Paula Ghaneh, Senior Lecturer in Surgery, Division of Surgery and Oncology, RLUH.

Associated Staff

Dr Peter Clark, Consultant in Medical Oncology, Clatterbridge Centre for Oncology, Director of the MCCR, Clatterbridge Cancer Research Trust.

Professor John Field, Professor of Molecular Oncology, University of Liverpool.

Mr Iain Stinson, Head of Computing Services Department, University of Liverpool.

Professor Paula Williamson, Director of the Centre for Medical Statistics and Health Evaluation, The University of Liverpool.

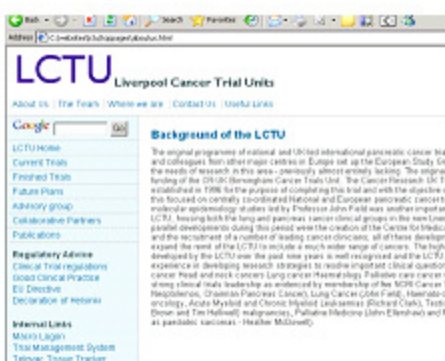
Consumer Involvement

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.

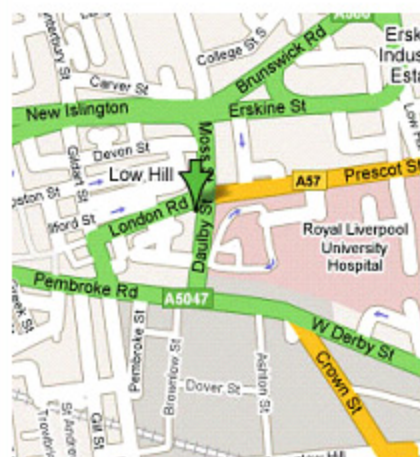
New LCTU Website & Email

Website. www.lctu.org.uk

Email lcu@liv.ac.uk



LCTU ADDRESS AND LOCATION



LCTU Address & Tel No

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 Cancer Research Centre
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 Liverpool
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