

# PEXIVAS

## Welcome to the winter edition of PEXIVAS newsletter!

As you all know, PEXIVAS trial opened enrolment in June 2010. Since the last newsletter in September the number of patients has doubled to 10. There are 15 active centres (UK, Europe and USA).

10 patients have been recruited so far. Congratulations and a big thank you to all of you who made the contribution towards this trial in its early stages.



Cambridge in the snow

### Centres that recruited the most patients:

Addenbrookes Hospital-  
Cambridge

5 recruited

St. Georges Hospital-  
London

2 recruited

## **PAX Gene Tubes for Biomarker Samples**

Just to remind all of you, biomarker samples will be collected at baseline (10 mls each for DNA, RNA, serum, plasma), 2 weeks (serum, plasma), 12 weeks (RNA, serum, plasma) and 52 weeks (RNA, serum, plasma). Once your centre becomes ready to recruit patients the Cambridge trial office will send you instructions on how to process these samples and a supply of PAX gene tubes. Thereafter, please check the expiry date on any unused tubes and contact us in Cambridge if you need more supplies. Please inform the Cambridge trial office if your centre does not have facilities to centrifuge or store these samples at minus 80 degrees Celsius before shipping them back to Cambridge.

## **Serious Adverse Event (SAE) reporting**

**SAEs MUST be reported, as soon as possible (and within 7 days) of occurrence.**

**SUSARs (suspected unexpected) due to glucocorticoid (-trial IMP) or plasma exchange, report within 24 hours.**

**FAX or scan/e-mail SAE form to +44 1223 586767 or trial co-ordinator Biljana Brezina (biljana.brezina@addenbrookes.nhs.uk).**

**US centers: please also report SAEs to the Vasculitis Research Consortium Office in Boston: Peter Merkel (pmerkel@bu.edu) and Carol McAlear (caking@bu.edu); Tel No: +1 617 414 2501, Fax: +1 617 414 2510.**

**Australian / New Zealand centers: please also report SAEs to the Australasian Kidney Trials Network: Alicia Morrish (a.morrish@uq.edu.au) and Donna Reidlinger (d.reidlinger@uq.edu.au); Tel No: +61 732405463).**

## **Upcoming PEXIVAS Investigators Meetings**

7th of April 2011: World Congress of Nephrology (ISN), Vancouver, Canada.

15th May 2011: ANCA Workshop, Chapel Hill, North Carolina, USA.

22nd of June 2011: European Renal Association, Prague, Czech Republic.

3rd of October 2011: UK glomerulonephritis meeting, Birmingham, UK.

**Sub-studies!**  
**Have you thought of proposing one?**

- Dr. Chen Au Peh of Adelaide (chen.peh@adelaide.edu.au). Exploration of the link between vasculitis and infection, and the effect of Toll-like receptor stimulation with peptide/nucleotide on ANCA production. The aim is to provide further insight into the link between infection and vasculitis.
- Dr. Wladimir Szpirt of Copenhagen (wladimir@szpirt.com) will assess the correlation between cyclophosphamide CYP2B6/CYP2C19 genotypes and adverse events (leucopaenia and infections) with the aim to design a better cyclophosphamide dose regimen.
- Dr. Janak DeZoysa (janak.dezoysa@waitematadhb.govt.nz) and Dr. Nuala Helsby (n.helsby@auckland.ac.nz) will examine the correlation between CYP2C19/CYP2B6 genotypes, and cyclophosphamide pharmacokinetics and treatment failure. There will be cooperation between the two centers.
- Dr. Peter Margetts of Hamilton, Canada (margetts@mcmaster.ca) will lead a study exploring the biology of circulating and renal tissue fibrocytes.
- Dr. Paul Brogan, London, UK (p.brogan@ich.ucl.ac.uk) neutrophil and endothelial microparticles, inflammation and vasculitis.

**Christmas and New Year Arrangements 2010-2011**

For eligibility and clinical questions contact [PEXIVASmedicalmonitor@nhs.net](mailto:PEXIVASmedicalmonitor@nhs.net). Alternatively, contact Dr. David Jayne on [dj106@cam.c.uk](mailto:dj106@cam.c.uk) or Biljana Brezina on [bjovanovska@nhs.net](mailto:bjovanovska@nhs.net).

Please note that the Birmingham Clinical Trials Unit will be closed from: **4.00pm Thursday 23rd December 2010 until 9.00am Wednesday 5th January 2011**. The online randomisation systems will be available as usual and the fax machine left switched on, so keep the patients coming...



VASCULITIS  
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VOLUME 1, ISSUE 3

We wish you all a very  
Merry Christmas  
and  
Happy 2011 Year!



Congratulations to Mike & Dorothy Walsh for an extra-special early Christmas gift: the arrival of their daughter Maddy!