

Birmingham Clinical Trials Unit



Renal Trials Portfolio Update

Issue 1

December 2010

Welcome to the Renal Trials Portfolio Update.
Merry Christmas and a Happy New Year to all
collaborators!

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GloMY study opens to recruitment 21st October 2010

GloMY is a randomised pilot trial of Myfortic for the treatment of primary proteinuric glomerulonephritis. The study is a national, multi-centre, randomised controlled open-label pilot trial of Myfortic plus short course steroids versus standard care in patients with proteinuric primary focal segmental glomerulosclerosis (FSGS) and IgA nephropathy (IgAN). Currently standard care is high-dose steroids a long course of steroids for patients with FSGS, and no treatment for patients with IgAN.

The aim of GloMY is to determine the feasibility of running a full-scale phase III randomised trial of Myfortic plus short course steroids versus standard care in patients with FSGS or IgAN, and to obtain preliminary comparative data on the efficacy of Myfortic plus short course steroids in inducing sustained response in patients with FSGS or IgAN.

The study seeks to recruit 100 patients over a period of 2 years with all patients being followed up for at least 2 years.

The GloMY Chief Investigator is Professor Lorraine Harper who is based at the Queen Elizabeth Hospital, Birmingham and the sponsor is the University Hospital Birmingham NHS Foundation Trust. The trial is funded by an Educational Grant from Novartis Pharmaceuticals UK Ltd.

The first patient was randomised into GloMY on 21st October 2010 by Professor Lorraine Harper.

11 centres across the UK have approval to randomise patients into GloMY. A further 14 centres across the UK are currently gaining the approvals necessary to take part in GloMY.

A very successful 1st GloMY Investigators Meeting was held in Birmingham on 1st October 2010.

PEXIVAS study opens to recruitment 8th June 2010

The PEXIVAS study is a clinical trial of plasma exchange (PLEX) and glucocorticoid (GC) dosing in the treatment of anti-neutrophil cytoplasm antibody (ANCA) associated vasculitis (AAV). This is an international, multicentre, randomised controlled trial which seeks to recruit 500 patients over a 5 year period.

The studies primary objectives are:

- To determine the efficacy of PLEX in addition to immunosuppressive therapy and GC in reducing death and end-stage renal disease (ESRD)
- To determine the non-inferiority of a reduced-dose GC regimen in reducing death and ESRD

The Chief Investigators are Dr David Jayne (UK and Europe), Dr Peter A. Merkel (USA) and Dr Michael Walsh (Canada). The study is funded by National Institutes of Health Research HTA in the UK and has various other funders globally:

Food and Drug Administration / National Institutes of Health and the National Institutes of Health, National Institute of Arthritis and Musculoskeletal and Skin Diseases (USA), National Health and Medical Research Council (Australia), Canadian Institutes of Health Research (Canada). PEXIVAS is sponsored by Cambridge University Hospitals NHS Foundation Trust.

So far 10 patients have been randomised into the study from 5 centres in the UK and Denmark. 15 centres now have approval to take part in PEXIVAS. PEXIVAS will be a truly global trial with over 100 centres participating from the UK, Europe, America, Canada and Australasia.

New PREDNOS trial to open soon!

The PREDNOS (PREDnisolone in NephroTic Syndrome) trial will assess long-term tapering versus standard prednisolone (steroid) therapy for the treatment of the initial episode of childhood nephrotic syndrome. PREDNOS is a UK multicentre randomised controlled double blind trial which seeks to recruit 224 children aged over 1yr, but less than 15yrs, over a 2 year period.

The aim of PREDNOS is to compare an extended course (16 week) tapering prednisolone regimen with the standard 8 week regimen as originally proposed by the International Study of Kidney Disease in Children (ISKDC).

The trial will take place in over 80 centres across the UK with the assistance of the Medicines for Children Research Network (MCRN).

The Chief Investigator is Dr Nicholas Webb of Royal Manchester Children's Hospital. The trial is funded by National Institute for Health Research Health Technology Assessment programme (NIHR HTA). The trial is co-sponsored by University of Birmingham and Central Manchester University Hospitals NHS Foundation Trust.

Currently applications are in progress to the relevant ethics, NHS and regulatory bodies and we hope that recruitment may start as early as February 2011.

Longer follow-up approved for ASTRAL trial patients

The ASTRAL trial is a study of angioplasty and stent for renal artery lesions.

ASTRAL opened in September 2000 and closed in October 2007 and recruited 806 patients, making it by far the largest published trial in atherosclerotic renovascular disease (ARVD). ARVD is a long-term progressive condition, so it is important not just to look at the short-term impact of revascularisation but to determine whether it has long-term benefits for patients.

The ASTRAL trial team now have ethical approval to follow up all surviving patients in ASTRAL for longer. Patients will be followed up annually for 10 years from the date the last patient was randomised (i.e. to 26th Oct 2017).

This will permit not only reliable evidence on the long-term effects of revascularisation on renal function and long term blood pressure control to be obtained, but will also allow investigation of its impact on major clinical end-points, such as need for dialysis and renal transplantation (which can have large cost-implications), vascular events and mortality.

BCTU Christmas and New Year Arrangements 2010-2011

Please note that the Birmingham Clinical Trials Unit, including the telephone randomisation service, will be closed from:

4.00pm Thursday 23rd December 2010 until 9.00am Wednesday 5th January 2011

The online randomisation service will remain available, as normal, 24hrs everyday over the Christmas and New Year period.

The renal trials team are always here to help. For further information about the renal trials please contact us:

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WEBSITES:

<http://www.bctu.bham.ac.uk/GloMY>

<http://www.bctu.bham.ac.uk/pexivas/>

<http://www.bctu.bham.ac.uk/prednos/>

<http://www.astral.bham.ac.uk/>

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PEXIVAS and GloMY Telephone

Randomisation (available 9am-5pm Monday
to Friday):

Tel: 0800 953 0274

PEXIVAS Online Randomisation

<https://www.trials.bham.ac.uk/PEXIVAS/>

Thank you for taking the time to read the latest newsletter

We wish you all a very Merry Christmas and a Happy New Year

