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PEXIVAS Trial

Dear PEXIVAS Investigators,

Thank you very much for taking part in the PEXIVAS trial. You will be pleased to know that as of today, 30th of January 2015, 496 patients have been recruited, out of our planed target of 500 patients. This is ahead of the planned recruitment schedule. As a trial of patients with an acute, complex, rare disease with organ- and life-threatening presentations running in 93 centres in four continents, this is a major achievement. It is over double the size of any vasculitis trial and one of the largest plasma exchange trials.

Because our predicted five year event rate (death or end stage renal disease, 32%) is lower than predicted when the trial was designed (38%) we are in danger of being underpowered for our primary hypothesis to test the efficacy of plasma exchange. This observation reflects recent registry data showing improved survival in patients diagnosed since 2000. We now propose extending the trial to recruit 700 patients and have submitted a grant to NIHR (UK) for an extension of funding, along with ethics and regulatory approvals in the UK. If granted, recruitment would continue to the end of 2016 and follow-up to the end of 2017, extending the whole trial by six months.

We have obtained **favourable ethical opinion,** and when we receive MHRA (UK regulatory authority) approval we will forward both to you to apply for local approvals. In the meantime we can only recruit 500 patients (4 more patients) and will have to suspend recruitment at that number.

David Jayne, Peter Merkel & Michael Walsh (Chief Investigators)
Biljana Brezina & Carol Mcalear (Trial coordinators)