

GAinS



The Intensive Care Society

Patron: HRH The Princess Royal

Newsletter November 2005

No. 1

Dear Colleague, This is the first of what will be a regular Newsletter to keep you informed of the progress of the Genomic Advances in Sepsis study (GAinS). We are also working on a GAinS Website that will eventually take over the newsletter function.

6 patients recruited! A good start with 3 centres having commenced patient recruitment (Royal Berkshire, Southend and the John Radcliffe). As Charles says, “only 6,994 to go!”

The “Postal Sample Delivery System” is working well; samples have arrived safely in the Genome Centre at the William Harvey Research Institute. DNA extracted is of good quality with high yield.

The paper CRF appears to be working well, but please do feed back to Chris Garrard, chris.garrard@ndm.ox.ac.uk Charles Hinds, C.J.Hinds@qmul.ac.uk or Paula Hutton, icugeneticresearch@orh.nhs.uk with any queries or comments.

Site Initiation To date there are 37 sites committed to participating in GAinS and 23 principal investigators have registered with COREC. <https://www.corecform.org.uk/AppForm/display/login.asp?b=4>

For those who have not yet had the opportunity to register with COREC please do so as soon as possible so that the ethics and

R&D forms may be transferred to you. If you are a bit bemused by the registration website or need log-on information, give Paula Hutton a call on 01865 222885 or email at: icugeneticresearch@orh.nhs.uk

Alternatively, if you have technical questions relating to completion of the ethics forms, the COREC IT personnel are very helpful on 01636 610060 or e-mail at: ithelpdesk@infonetica.co.uk. Otherwise please contact Paula Hutton on 01865 222885.

Paula has made 6 site visits with Investigator Files and Patient Recruitment Packs. These packs contain CRFs, consent forms, blood sample kits and mailing boxes, everything you need to recruit a patient! Several sites are now just waiting for approval before starting study activities. Paula, Charles and Chris will be visiting sites to go through the study protocol and deliver the patient recruitment packs and site investigator files.

At the same time, Paula will be contacting PI's to ascertain the stage of ethics/R&D application for their sites. This is to prioritise pack delivery to enable sites to start recruiting as soon as they have full approval.

GAinS has been registered with ClinicalTrials.org. This NIH registry was set up for all new clinical trials to facilitate the publication of results in most of the major medical journals. To see the NIH Trials registration, go to:

<http://clinicaltrials.gov/> - then type in “sepsis, uk” as search terms. If your site is not

Identified let us know and we'll update the entries.

Funding We have been successful in securing further funding in addition to the original award from the Sainsbury Family Trust. This generous award should allow us to recruit up to 2,500 patients. We have been exploring resubmission to the major funding bodies in the next 6-9 months as well as other sources.

UKCCG Meeting We plan to arrange a meeting for all UKCCG investigators from all the recruiting centres in March 2006. This day-long meeting will probably be held in the Wellcome Trust Centre for Human Genetics in Oxford and include 2 or 3 presentations on genomics and related topics from international experts as well as UKCCG business. The meeting will be followed by dinner in one of the Oxford colleges (with a bit of luck).

GAInS and GenOSept Charles Hinds and Chris Garrard have worked hard with GenOSept to ensure concordance of the GAInS and GenOSept protocols. Apart from GenOSept recruiting pancreatitis and meningococcal disease in addition to CAP and faecal peritonitis, the protocols and CRFs are identical. Both studies will be able to use a common eCRF (electronic case report form) and there will be a set of information sheets, consent forms etc applicable to both studies.

This will enable sites to participate in both the UK and European studies but they will only need to approach patients or their next of kin once for consent. Ethics approval for GenOSept is awaited. For every patient recruited to GenOSept or GAInS/GenOSept there will be a payment of 100 euros to the study site.

Thanks to you all for your support of GAInS

**Chris Garrard
Charles Hinds
Paula Hutton**