GAinS

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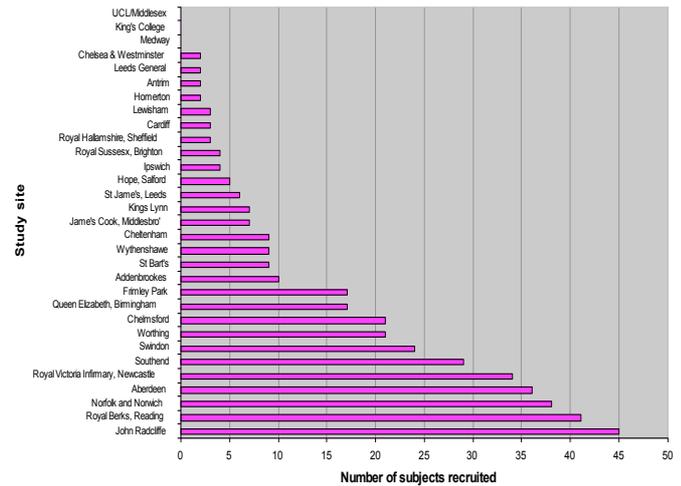
Newsletter August 2007   No. 5

Dear Colleagues,

409 patients with faecal peritonitis (145) and community-acquired pneumonia (186) have now been recruited to GAinS. Recruitment rates into GAinS, for individual centres are shown below:

Site	Recruits up to 23.08.07
John Radcliffe	45
Royal Berks, Reading	41
Norfolk and Norwich	38
Aberdeen	36
RVI, Newcastle	34
Southend	29
Swindon	24
Worthing	21
Chelmsford	21
Queen Elizabeth, Birmingham	17
Frimley Park	17
Addenbrookes	10
St Bart's	9
Wythenshawe	9
Cheltenham	9
Jame's Cook, Middlesbro'	7
Kings Lynn	7
St Jame's, Leeds	6
Hope, Salford	5
Ipswich	4
Royal Sussex, Brighton	4
Royal Hallamshire, Sheffield	3
Cardiff	3
Lewisham	3
Homerton	2
Antrim	2
Leeds General	2
Chelsea & Westminster	2
Medway	0
King's College	0
UCL/Middlesex	0

Recruitment to GAinS/GenOSept up to 23.08.07

There has been a bit of an August lull, not surprisingly, but we expect numbers to pick up again in September. Once again our sincere thanks to all the centres, investigators and research nurses for your commitment to the project.

New Centres Welcome

We continue to get enquiries from new sites interested in GAinS and we enthusiastically welcome newcomers to the study. So if you have a neighbour who you think would be a good addition to GAinS/GenOSept, please let us know. Just a name, an email address or telephone number is all we need.

1000 patients in GenOSept

Recruitment to GenOSept Europe-wide has exceeded 1000 patients as more centres come on-stream. Almost all GAinS centres in the

UK have also joined the GenOSept project. Just to remind you, GenOSept is recruiting the same diagnostic groups of patients as GAinS (community acquired pneumonia and faecal peritonitis) with the addition of pancreatitis and meningococcal disease. Recruiting centres will receive 100 euros for every patient recruited to GenOSept. The electronic case report form (eCRF) is available for patients recruited to both GenOSept and GAinS. Log onto the eCRF at: https://www.genosept.eu/index.ecrf/ Your username and password will be provided by the GenOSept central office. If there are problems getting passwords email Paula Hutton at: ICUgeneticresearch@orh.nhs.uk

The UK leads the league table below with 212 patients recruited.

Belgium	122
Czech Republic	105
Croatia	8
Germany	104
Ireland	68
Israel	11
Italy	77
Poland	36
Spain	160
United Kingdom	**212**
Serbia	14
Estonia	13
France	36
Greece	3

The eCRF is for patients recruited to GAinS/GenOSept. Those few centres that are recruiting only to GAinS should continue to use the paper CRF. Completion of the paper CRF for GainS/GenOSept is optional but if used it must be photocopied and the original sent to Oxford (as for the GainS only patients).

Please will all those who wish to participate in GenOSept complete their LREC and R&D applications so that you will be ready to commence recruiting as soon as you receive the recruitment packs and your password for the eCRF.

Reimbursement for GenOSept patients

UK centres have been receiving reimbursement for patients recruited to GenOSept The first payment is made after the 1st 5 recruits and from then on payments are made on a quarterly basis. however. Payments can only be made once the Letter of Agreement has been completed and a copy returned to Prof Stuber in Bonn (you need to keep the other copy at your site).

eCRF In general the eCRF has proved to be robust, reliable and intuitive. The French database company, Lincoln, have worked on improving the database and we are interested in your views for further improvements. The UK still only recruits patients with faecal peritonitis while non-UK European centres are recruiting other forms of peritonitis as well (e.g. upper GI perforations, biliary peritonitis). The eCRF is being adjusted to allow these other forms of peritonitis to be identified (non-UK centres only). Please only recruit the faecal peritonitis patients – we want to maintain the tight phenotype grouping in the UK and we do only have ethics approval for the FP patients.

Data Quality Assurance (QA)
There is no doubt that the biggest time commitment to GAinS/GenOSept is completion of clinical data in the CRF – this information is vital to the success of our project. The joint GAinS/GenOSept projects are now investing in an active QA programme to ensure accuracy and completeness of the eCRF data. Alex Smith and Paula Hutton, based in Oxford have the arduous task of reviewing the eCRFs from across Europe! If errors or omissions are found a data query will be

created in the eCRF patient record and you will be contacted by email requesting data correction. Thanks to your efforts the CRF's have generally been completed fully and accurately. Please do contact us if anything needs clarification. Penny Parsons continues to work on the returned paper CRF's for the study.

Some investigators have been recording **all** courses of **antibiotics** prescribed during the patients ICU stay. In some cases these antibiotics are being given for a purpose other than those related to the admission diagnosis of FP or CAP. While we applaud the investigators diligence and hard work we only want to be able to assess the "appropriateness" of antibiotics given for FP or CAP. So if a patient developed a urinary tract infection or VAP later in their ICU stay, the antibiotics given for those infections need not be recorded.

Grant applications and funding
We are keenly awaiting the adjudication of our MRC application due in mid-October. In the meantime funding for the National Coordinator and QA support continues and is a vital part of the success of GAinS/GenOSept. Other applications have been submitted for Functional Genomics (Dr Julian Knight).

GAinS website
Just a reminder of the website for the GAinS study. The URL is: http://www.ukccg-gains.org/
This contains information about the study, membership of the group and contact details, links to other websites (e.g. GenOSept), recruitment rates, questions and answers etc.

UKCCG Meeting
The annual meeting of the UK Critical Care Genomics Group was held at the Wellcome Trust

Centre for Human Genetics, Oxford, on the 6th June 2007. It was well attended by investigators and research nurses from across the country.   Progress reports for GAinS/GenOSept were delivered by Prof Frank Stuber (Bonne University), Prof Charles Hinds, Chris Garrard and Paula Hutton. This was followed by a first class series of presentations by Frank Stuber (Genomics of Sepsis), Andrew Morris (Wellcome Trust Case Control Consortium), Adrian Hill (Genome-wide association) and Patricia Munroe (BRIGHT study). There followed an excellent dinner at a local restaurant. This years meeting was generously supported by Lilly Inc.

Next year's meeting is expected to be held in London. We'll try to give you as much notice as possible.

Thanks
Thanks once again, for your continued support and participation. The success of the recently published Wellcome Trust Case Control Consortium has highlighted the enormous value of collections such as GAinS and GenOSept. The advent of genome-wide association studies has changed much of how we will address the mysteries of sepsis. Fortunately, our study design positions us ideally to take advantage of these new developments.

CRF questions
CRF questions and answers can be found on the UKCCG website http://www.ukccg-gains.org/ – select 'technical information', Of course you are welcome to contact us at any time by phone or email with any questions you may have about the studies., please see contact details below.

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