

G A i n S



Newsletter October 2009 No. 7

Site	CAP/FP/P/MD Recruits up to 12.10.09
Royal Berks, Reading	122
John Radcliffe	99
Norfolk and Norwich	94
Aberdeen	90
Royal Sussex, Brighton	50
RVI, Newcastle	48
Leicester	46
Chelmsford	46
Southend	43
Worthing	43
Swindon	42
Frimley Park	27
Barts and the London	26
Kings Lynn	25
Cheltenham	21
Addenbrookes	20
Queen Elizabeth, Birmingham	18
James Cook, Middlesbro'	18
Wythenshawe	17
St James, Leeds	16
Charing Cross, London	13
Lewisham	6
UCLH	5
Hope, Salford	5
Ipswich	4
Chelsea & Westminster	4
The Manor, Walsall	4
Royal Hallamshire, Sheffield	3
Cardiff	3
Colchester	3
Homerton	2
Antrim	2
Leeds General	2
Medway	0
King's College	0
The Whittington, London	0

828 patients in GAInS

By mid September, 828 patients with faecal peritonitis (340) and community-acquired pneumonia (488) had been recruited to GAInS.

Recruitment numbers for GAInS and GenOSept, for individual centres are shown on the left:

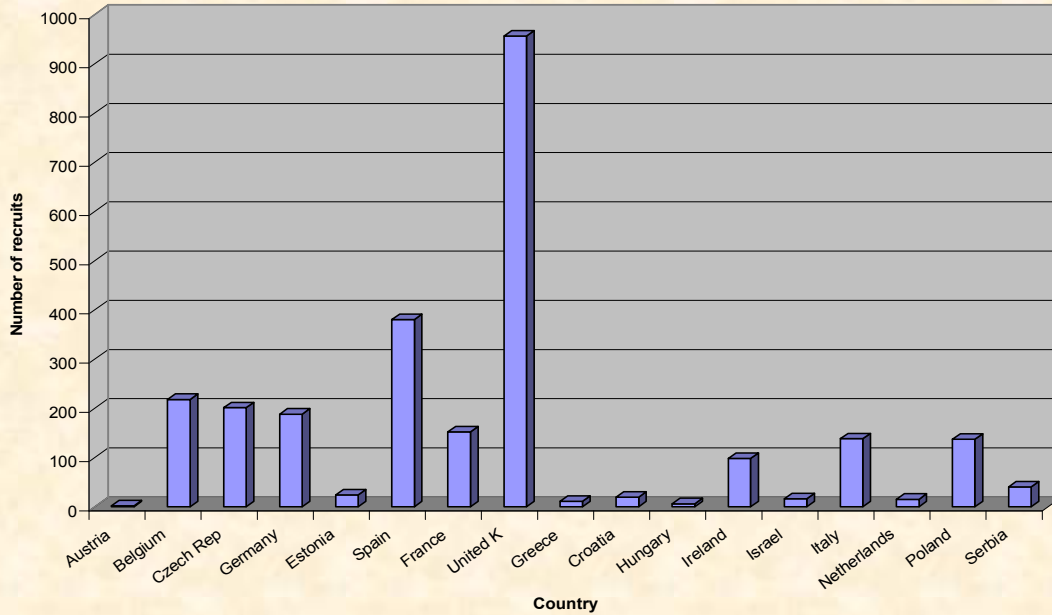
*A fantastic effort from
all the centres and our
thanks to all
investigators and
research nurses for
your commitment to
the project.*

New Centres Welcome

We have a new site, Huddersfield and Calderdale, about to 'go live' and look forward to their contribution to the study. If you know of a colleague who you think would like to join GAInS, have them contact us at: ICUgeneticresearch@orh.nhs.uk

2601 patients in GenOSept

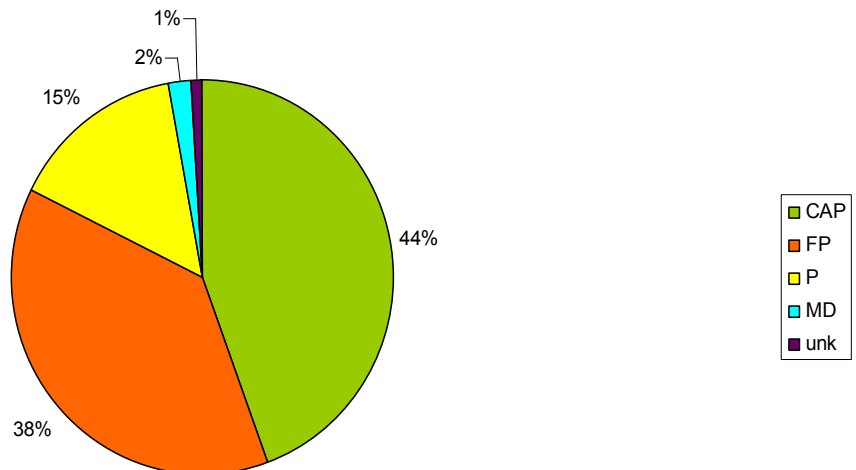
GAINs/GenOSept study recruitment to 12.10.09



Recruitment to GenOSept Europe-wide has exceeded 2601 patients.

82% of the patients have a diagnosis of CAP or FP.
The unknown 1% represents those for whom the diagnosis has not yet been confirmed.

Disease frequency in patients recruited to GenOSept/GAINs up to October 2009



UK Recruitment

The UK continues to lead the European league table (below) with 956 patients

Austria	2
Belgium	218
Czech Republic	201
Croatia	19
Germany	188
Hungary	6
Ireland	98
Israel	16
Italy	138
Netherlands	15
Poland	137
Spain	380
United Kingdom	956
Serbia	40
Estonia	24
France	152
Greece	11

Serial Samples

Please complete and return your electronic logs to Paula at the beginning of each month; this is important so that we can ensure the NIHR portfolio accrual data is kept up to date which then enables your local networks to track recruitment activity (more patients = more support from your network!).

GAinS Newsletter No. 7 – Oct 2009

Patient Recruitment packs

When you are down to your last 3 patient packs please email Charles Mein c.a.mein@gmul.ac.uk to request a new set.

For serial sample kits please email Paula Hutton ICUgeneticresearch@orh.nhs.uk

Data analysis strategy

A genome-wide association analysis is currently being performed on a cohort of 2000 GenOSept/GAinS patients with CAP or peritonitis.

Replication will be undertaken using large cohorts of septic patients collected by other groups who have agreed to collaborate.

A number of candidate gene association studies are underway or planned in collaboration with UK investigators. These include a large CAP study that has recruited patients treated in the community and in hospital but not requiring intensive care, a study of mitochondrial haplotypes and another investigating genetic predisposition to ALI/ARDS.

Gene expression arrays have been obtained for an initial cohort of patients from whom serial white cells were collected. As a first step we are analysing differences in gene expression between surviving and non-surviving patients with CAP. Preliminary results are promising and will be presented at the State of the Art meeting in December. In the longer term we plan to investigate the influence of DNA sequence variation on changes in gene expression. For this we need at least 135 CAP patients and 135 FP patients with serial samples of white cells. So please keep recruiting!

Data Quality Assurance (QA)

The joint GAinS/GenOSept projects are still being actively subjected to a QA programme to ensure accuracy and completeness of the eCRF data. Alex Smith and Paula Hutton, based in Oxford, have reviewed over two and a half thousand eCRFs from across the UK and Europe! Errors or omissions create alerts which are used to generate email data queries (DQs). More than 9,000 queries have been sent and 91% of DQs have been resolved. Do contact us if anything needs clarification. Please respond to the data queries as soon as possible so that the data set of patients recruited so far can be used in the analysis which has now commenced. It is vital that we have accurate data for the phenotype/genotype analysis.

NIHR/UKCRN

The NIHR has included the serial sampling aspect of the GAinS study in the portfolio. This means that each study centre is eligible to apply for funding to support this element of GAinS research activity. Please do contact your local Research and Development department to ask if you are entitled to some

H1N1 (swine flu)

We are interested in examining genetic influences on susceptibility to severe influenza and on mortality in these cases.

Please don't forget to recruit patients with H1N1 to GAinS if they fulfil the inclusion criteria for CAP.

Please ensure that you:

1. State the type of virus in the CAP page of the eCRF and the test used to confirm the diagnosis in the comments box.
2. Record the antiviral treatment in the antibiotic page of the eCRF (you will need to add this as a comment as the H1N1 antivirals are not included in the pick list).
3. Please enter if the patient is obese in the Modified Charleson Index (co-morbidities).

Collaborative Research

Do you have any original research questions that could be answered by examining the GAinS/GenOSept data? If so, you might wish to discuss the possibility of collaborative research with Prof Charles Hinds or Dr Chris Garrard.

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, as well as links to other websites.

eCRF

The electronic case report form (eCRF) is still available for patients recruited to GAinS. Log onto the eCRF at:

<https://www.genosept.eu/index.ecrf/>

Continue to use your username and password as provided by the GenOSept central office.

If you require a password for new members of your team please email Paula Hutton at:

ICUgeneticresearch@orh.nhs.uk

GAinS study continues...

Patient recruitment for GenOSept ended at the end of December 2008.

Recruitment to GAinS will continue until at least December 2010.

Thank you!

We have made great progress with the collections for both GAinS and GenOSept. This is entirely due to the enormous efforts of the Investigators and Research Nurses in each of the UK and European ICUs.

CRF questions

Frequently asked 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.

Contact details

Charles Hinds

Tel: 0207 601 7526

c.j.hinds@qmul.ac.uk

Chris Garrard

Tel: 01865 220621

chris.garrard@ndm.ox.ac.uk

Paula Hutton

Study Co-ordinator

Tel: 01865 222885

ICUgeneticresearch@orh.nhs.uk

Charles Mein

Genome Centre Manager

Tel: 0207 882 5776

c.a.mein@qmul.ac.uk