



Scottish Early Rheumatoid Arthritis (SERA) Inception Cohort and Biobank NEWSLETTER

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WELCOME to the first edition of the SERA newsletter which will be used to provide quarterly updates on study progress and new developments. As you are aware participant recruitment started in April 2011, but with site set-up activities and the implementation of the SERA LIMS there have been limited opportunities to keep colleagues and collaborators updated on progress. However, we intend to rectify this through a combination of quarterly newsletters and regular updates to the SCAR website which we hope will keep colleagues better informed.

SERA RECRUITMENT

We have had a slow though steady start to the project but are now making great progress and at the end of August we have recruited our **500th** study participant. We intend to mark this fantastic milestone by presenting the referring doctor and recruiting nurse with a bottle of something fizzy and alcoholic!

Monthly recruitment figures are extracted from the SERA e-CRF and uploaded on to the UKCRN portal. Ann Tierney distributes monthly recruitment figures to all SERA collaborators. Please let us know if you wish to be included on the distribution list for these reports.

SERA Study Update:

THANKS TO YOUR HARD WORK AND SUPPORT...

- 497 patients have been enrolled in SERA since 01/04/2011
- We are recruiting from 21 sites within 10 Scottish NHS Health Boards
- Approx 14,000 blood & urine aliquots are now stored in the SERA LIMS

NHS Boards



SERA recruits from 21 sites within 10 Health Board areas

Please continue to support SERA by screening all new RA/UA patients for inclusion in the SERA cohort

Eligibility criteria are:

- New diagnosis of Rheumatoid arthritis
- New diagnosis of Undifferentiated Arthritis
- ≥ 1 swollen joint
- Aged 18 years and over
- Willing and able to give informed consent
- Ideally DMARD naive, though we can recruit patients who have been taking DMARD for 1 month or less

SAMPLE COLLECTION

One of the major achievements of 2011 was the development and implementation of a bespoke laboratory information management system (SERA LIMS). The LIMS software is hosted and supported by the Robertson Centre for Biostatistics and enables us to manage sample tracking from multiple sites and for the storage and eventual retrieval of SERA samples. This piece of work was crucial to the effective operation of the study as on completion of SERA there will be approximately 150,000 samples and aliquots stored within the SERA Biobank.

OTHER LIMS NEWS.....

The SERA study is currently supporting two biorepository hubs; one at the Western General Hospital in Edinburgh which processes samples from NHS Lothian and NHS Borders and the other is held within NHS Greater Glasgow and Clyde which receives and processes samples from the remaining SERA sites.

Plans are afoot to set-up another hub within the pathology department at Ninewells Hospital in the autumn of 2012. This NHS Tayside hub will receive and process samples from NHS Fife, Perth Royal Infirmary and Ninewells Hospital.

UPDATE ON SERA COHORTS

Scottish Nested Arthritis Protocol

SNAP Recruitment target = 200 patients

January 2012 saw the launch of the Scottish Nested Arthritis Protocol (SNAP) cohort.

Recent therapeutic advances have considerably improved outcomes for patients with RA. However, the prognosis for RA is still highly variable and there is still an urgent need for biomarkers that will define patients that will progress as compared with those that will either remit spontaneously or do so upon early therapeutic intervention. The ability to tailor individual therapy based on the patients genotype and phenotype so that the most appropriate treatment strategy can be started as early as possible would create the best opportunity to maximize positive outcomes.

The SNAP cohort aims to discover whether it is possible to identify markers for disease progression through a combined approach of analysing clinical and radiological data along with detailed analyses of blood samples using immune cell phenotype evaluation by analytical fluorescent activated cell sorting (FACS), transcriptional profiling, and cytokine / chemokine measurements.

It is anticipated that analysis of this cohort will aid the development of precision medicine and the identification of putative therapeutic targets.

- SNAP recruitment is running in NHS GGC and NHS Grampian only
- To date 62 SERA patients are enrolled in the SNAP cohort
- SNAP x-rays are taken at the baseline visit as part of standard NHS care with an additional x-ray at the 6 month follow-up visit
- An additional 47ml of blood is taken for deep immunotyping by FACS
- Immediately after collection SNAP bloods are transferred to the research labs
- Isolated peripheral blood mononuclear cells are labelled with 60 fluorescently labelled cell markers
- Samples are acquired with a state-of-the-art 4 laser bench top flow cytometer fitted which can simultaneously detect 16 fluorescent colours.
- Subsequent data analysis allows us to identify over 488 cell subsets.



Biologic Cohort

Recruitment target = 120 patients

Amendment 11 saw approval for the addition of a control cohort of 120 RA patients starting TNF inhibitors as part of routine treatment.

This cohort represents patients with severe, established disease that is refractory to conventional drugs. It will facilitate the identification of biomarkers of poor prognosis and drug resistance that can then be applied prospectively in the SERA inception cohort. The disease assessments, data collected and samples taken are the same as for the patients in the inception cohort.

Patients will attend for baseline and at 6 months (or at discontinuation of TNF, whichever is sooner).

The SERA e-CRF is being updated to support TNFi data collection. In the meantime, a paper CRF will be used for data collection. Electronic copies of the TNFi paper CRF have been sent to all SERA nurses.

First Degree Relative Controls

FDR Recruitment target = 250 patients

First Degree Relative control recruitment was rolled out in February 2012 with centres in NHS Greater Glasgow and Clyde and NHS Grampian recruiting.

Patients are asked to pass on an invitation letter and patient information sheet to a first degree relative (non RA) who would be prepared to consider donating blood to the biobank.

In June, we extended FDR recruitment to all SERA sites. Paul Allcoat from NHS Fife was the first nurse to recruit a control patient, impressively recruiting 2 relatives in the one week! Well done, Paul and thanks.

Study Support

- For any queries relating to study eligibility please direct these to Duncan Porter Duncan.porter@glasgow.ac.uk or the SERA project coordinator, caron.paterson@glasgow.ac.uk
- Replenishment of study supplies can be arranged through the Glasgow biorepository staff, Robin Thomson and Angela Rinaldi Robert.thompson@glasgow.ac.uk angela.rinaldi@glasgow.ac.uk. **Please note that Mondays** are relatively quiet days in the biorepository and therefore the best day to pick and dispatch supplies. Orders received before lunchtime should be shipped that afternoon.
- If you experience any issues using the SERA e-CRF report this via the SERA IT Support at seraitsupport@glasgow.org - remember to cc caron.paterson@glasgow.ac.uk

Contact Details

Duncan Porter
Senior Lecturer and Honorary Consultant
Rheumatologist
Gartnavel General Hospital
1053 Great Western Road
Glasgow, G12 0YN

☎ Office 0141 211 3429

✉ Email: duncan.porter@glasgow.ac.uk

Caron Paterson
SERA Project Coordinator
Institute of Infection, Immunity &
Inflammation
University of Glasgow
Room B513, Sir Graeme Davis Building
120 University Place
Glasgow, G12 8TA

☎ Office 0141 330 7655

☎ Mobile 07734 816598

✉ Email: caron.paterson@glasgow.ac.uk