

SIRAS

Scotland and Ireland Registry
for Ankylosing Spondylitis

UPDATE NEWSLETTER – JULY 2011

Investigators

On behalf of the SIRAS Steering Committee:

Epidemiology Group, Institute of Applied Health Sciences, University of Aberdeen

- Professor Gary Macfarlane – Professor of Epidemiology
- Dr Gareth Jones – Senior Lecturer in Epidemiology
- Elizabeth Jones – SIRAS coordinator

Centre for Rheumatic Diseases, Glasgow Royal Infirmary University Trust

- Professor Roger Sturrock – Emeritus Professor of Rheumatology / Honorary Senior Research Fellow; also Honorary Professor of Rheumatology, University of Aberdeen.

Inverclyde Royal Hospital

- Dr David Marshall – Consultant Rheumatologist

For more information about SIRAS, please contact

Elizabeth Jones – SIRAS coordinator
Epidemiology Group, Institute of Applied Health Sciences
University of Aberdeen School of Medicine and Dentistry
Polwarth Building, Foresterhill, Aberdeen, AB25 2ZD

Tel: 01224 552 495

E-mail: siras@abdn.ac.uk

INTRODUCTION AND HEADLINES

Enclosed is the latest update from SIRAS including recruitment figures correct to the end of June, and a brief update on current and future plans. Recruitment is ongoing, not only the audit data and baseline questionnaire, but we are now also collecting follow-up data from some participants, and are starting to collect saliva samples to feed into a large international replication study on the genetics of ankylosing spondylitis.

We say goodbye to Flora as SIRAS coordinator, and welcome to Elizabeth. (This changeover actually occurred a number of months ago, but this is the first newsletter since then.) In addition, we welcome Peter Worthington, as a patient representative, on to the steering group.

As usual, we welcome any comments or queries to siras@abdn.ac.uk.

Best wishes,



Dr Gareth Jones
Senior Lecturer in Epidemiology – University of Aberdeen

PHASE 1

Summary of progress to date

Recruitment is continuing well and, correct to the end of June, we have extracted data on 1392 patients, from thirteen centres. Pressing ahead in the centres not currently recruiting has been on hold, while we develop new instruments for the new Extra-Spinal Manifestations study (see below). However, preparations for this are now almost complete, and we hope to start recruitment in the near future.

Cumulative recruitment is shown in Figure 1, and, also, a hospital-by-hospital breakdown of recruitment is shown in Table 1.

Figure 1 – Cumulative recruitment to Phase 1

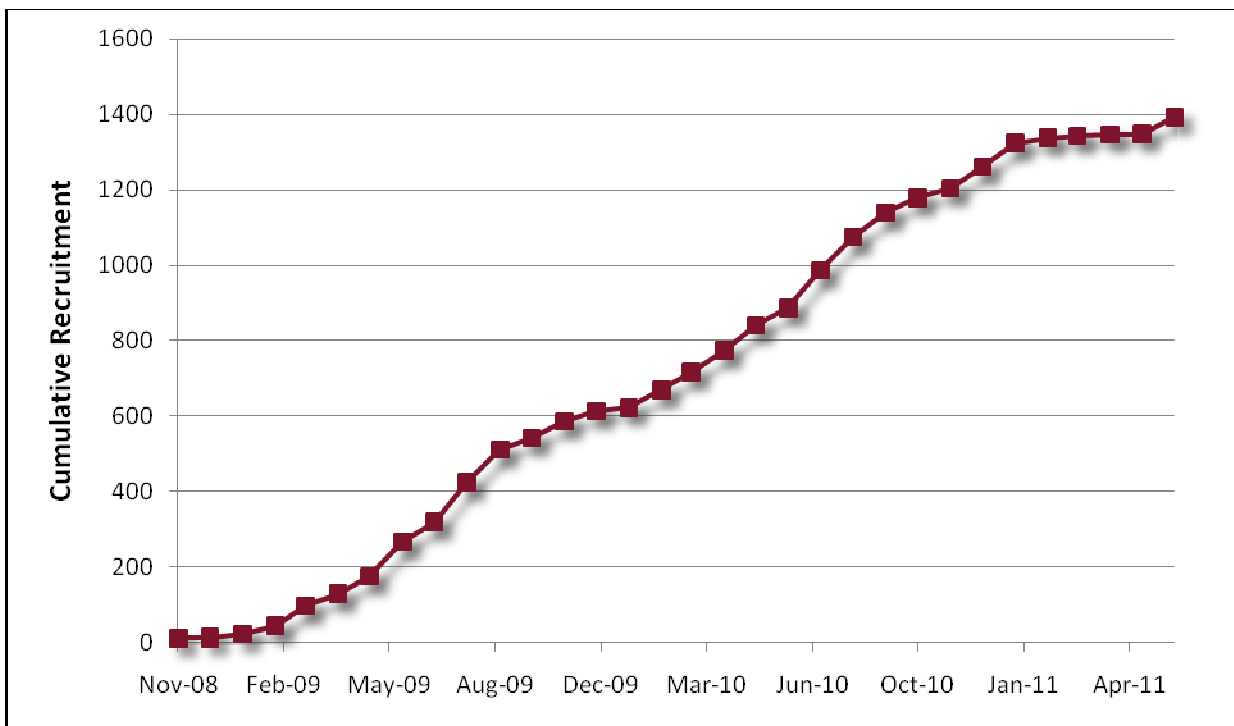


Table 1 – Breakdown of Phase 1 recruitment

	Glasgow Royal Infirmary	Gartnavel General Hospital	Inverclyde Royal Hospital	Southern General Hospital	Stobhill Hospital	Ayrshire & Arran	Victoria Infirmary	Aberdeen Royal Infirmary	Raigmore Hospital, Inverness	Fife Rheumatic Diseases Unit	Borders General Hospital	Monklands Hospital	Edinburgh	Total
Nov-08	11	1												12
Dec-08	2	1												15
Jan-09	4		4											23
Feb-09	4	7		10										44
Mar-09	23	22	8											97
Apr-09	17	2		9				4						129
May-09	7		10	12				17						175
Jun-09	26	16			5			45						267
Jul-09	10	11	8					23						319
Aug-09	28		6	10				3	58					424
Sep-09	22	21		12	7			4	21					511
Oct-09	7	4	6		5			9						542
Nov-09	30				7			7						586
Dec-09	10		8		7			2						613
Jan-10		1						8						622
Feb-10	5	2			6			12		22				669
Mar-10		9			2			5		31				716
Apr-10		17	10		1			8		21				773
May-10		14	8	5	3			30		7				840
Jun-10		14						12		20				886
Jul-10		22	5	2				0		17	32	21		985
Aug-10		29				4		2		35	3	16		1074
Sep-10		2				14		1		10		16	21	1138
Oct-10				4		3		1		21			11	1178
Nov-10				9		6		2					8	1203
Dec-10		18		11		7		2					19	1260
Jan-11		42				6		3					12	1323
Feb-11		9				2							3	1337
Mar-11						2							3	1342
Apr-11						1							3	1346
May-11						1								1347
Jun-11			3		10	3	29							1392
Total	206	264	76	84	53	49	29	200	79	184	35	53	80	1392

Analysis / Output

An abstract has been submitted to the American College of Rheumatology annual scientific meeting, based on SIRAS data, and we are currently waiting to hear whether this has been accepted.

- Jones GT, Morton L, Lambert CM, Richmond R, MacDonald AG, Jones EA, Sturrock RD, Hunter J and Macfarlane GJ: Fatigue: prevalence, correlates and consequences. Results from the Scotland and Ireland Registry for Ankylosing Spondylitis.

In brief, the aims of this analysis were to determine the prevalence of moderate / severe

fatigue; the demographic / clinical characteristics of these patients; and its socio-economic consequences. Among SIRAS participants, we found that fatigue was common: only 1.6% reported no fatigue; and nearly half (46%) reported moderate / severe fatigue. Fatigue was strongly associated with being unemployed, poor physical and mental functioning and quality of life. It was, however, associated with only some measures of disease activity. Understanding the aetiology with a view to optimising management remains a priority.

PHASE 2

Summary of progress to date

Recruitment is continuing for the centres where Phase 1 had been completed, still with a response rate of around 55%. We currently have baseline questionnaires returned from 552 patients, providing data on self-reported measures of function, general health, and quality of life, etc.

Patients from a number of centres are also now receiving their first follow-up questionnaire. These are being sent to baseline questionnaire participants who gave their permission to be

contacted about additional studies relating to AS. By definition, this comprises a more select group of participants who are keen (or, at least, keener) to participate in research. Accordingly, the response rate from the follow-up questionnaires is more positive – currently around 70%.

Follow-up questionnaires will continue to be sent out to patients on the anniversary of their baseline questionnaire.

OTHER NEWS

Extra-Spinal Manifestations of Ankylosing Spondylitis

Abbott have funded an add-on project to SIRAS to provide further information on:

- Disease progression and natural history of ankylosing spondylitis;
- Extra-spinal manifestations of the disease – both their occurrence, and the relationship

between them (either individually or combined) and quality of life; and

- The effect of the disease on work.

Some of this will be achieved by an analysis of the data already available on SIRAS subjects – both data from the audit phase and the self-completion questionnaires. However, some will require additional data collection from the clinical notes. As such, it will be necessary to go back to the medical records of all patients already on the database to collect – for example – data on all BASDAI information available, not solely the most recent clinic visit.

What this means in practice, of course, is that we will be revisiting all centres to re-audit clinical notes. The data collection forms have changed accordingly, to accommodate a number of pieces of clinical information, hitherto not collected. We have also taken this opportunity to revise our data collection forms in light of feedback from the nurses undertaking data collection.

Genetics of ankylosing spondylitis

In addition to receiving follow-up questionnaires, participants who gave their permission to be contacted about additional studies relating to AS are also being invited to donate a saliva sample for genetic analysis.

A genome wide association study of ankylosing spondylitis has already been completed and has identified a number of genes contributing to the disease. Work is currently underway to try to replicate these findings, and is being lead by Professor Paul Wordsworth at the University of Oxford, and Professor Matthew Brown at the University of Queensland. Saliva samples from the SIRAS participants will be feeding into this initiative.

The participant response rate for this part of the study is also very positive. Currently, 70% of participants invited to participate have indicated their willingness to do so and, accordingly, we are currently mailing the sample collection kits to these patients.

British Society for Rheumatology Ankylosing Spondylitis Register (BSR-ASR)

Preparations are continuing for the BSR-ASR, although we are still awaiting the green light from the BSR with respect to funding. Unlike SIRAS – a disease registry, recruiting all patients with ankylosing spondylitis – the BSR-ASR is a large cohort study (like the BSR-BR) which will recruit 650 AS patients going on to anti-TNF α therapy, and 650 patients not exposed to these drugs.

The burden upon BSR-ASR recruiting centres will be slightly different to that of SIRAS. In essence, it will be similar to the requirements for the BSR-BR, except that research nurse time will be provided. More information about precisely what will be involved will be given at the forthcoming SSR meeting in Troon (October 28th), and we hope that many of the centres in Scotland currently recruiting patients to SIRAS will also wish to participate in the BSR-ASR.

Change of staff

Although she has been in position now for a while, this is the first newsletter since her appointment, so I would like to introduce Elizabeth Jones, the new SIRAS coordinator. This is essentially a 'home grown' appointment: Liz has recently completed her PhD in the Epidemiology Group at the University of Aberdeen (she should graduate in November this year). She officially started work in February, working alongside Flora, who left in May. Elizabeth is available on siras@abdn.ac.uk.

Flora, as many of you may know, was SIRAS coordinator by day, while studying pharmacy at Robert Gordon University by night (or perhaps the other way around). Her MPharm thesis, conducted late in 2010, was not on SIRAS data *per se*, but was in the area of ankylosing spondylitis. She reviewed and summarised the existing published evidence to determine whether, among patients with ankylosing spondylitis, the risk of syndesmophyte formation is greater at sites of vertebral corner inflammation. In brief, she found that the risk of syndesmophyte formation over a 2yr period is more than doubled at vertebral corners that exhibit inflammation, strongly supporting the hypothesis that inflammatory vertebral lesions lead to ankylosis. Her pooled estimate of this effect, across six studies published to date, is lower than many of the previous estimates and, for the first time, describes the relationship in terms of risk.

Not only did this work contribute to successful degree completion, but was also presented as a poster (indeed, selected for a poster tour) at EULAR earlier this summer.

- Joyce F, McHattie L, Sturrock RD and Jones GT: Vertebral corner inflammation in ankylosing spondylitis and syndesmophyte formation. *Ann Rheum Dis* 2011; 70 (Suppl 3): 513

In addition, she was awarded the Royal Pharmaceutical Society of Great Britain best student research project, 2011.

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