

SIRAS

Scotland and Ireland Registry
for Ankylosing Spondylitis

UPDATE NEWSLETTER – JULY 2009

Investigators

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INTRODUCTION

Welcome to the inaugural SIRAS newsletter. Arguably long overdue, the main aim of the newsletter is to keep everyone updated with study progress and development – in particular, study recruitment.

I will endeavour to send it out monthly, to allow you to monitor recruitment (if you so wish) and, while I will try to put together something more substantial every 6 months or so, on a monthly basis there is probably no need for a large “issue”, so it will normally be a shorter document limited to key information.

In Aberdeen we are delighted with SIRAS progress. The study was quite a long time in gestation and it's great to be recruiting patients and see the numbers creeping up.

We are also delighted that NASS, the National Ankylosing Spondylitis Society, have agreed to advertise Phase 2 of SIRAS on their website (<http://www.nass.co.uk/public/news.htm>). They have also agreed to provide a short feature on the study in a future newsletter. This will serve to advertise the study and – hopefully – help boost participation in Phase 2, when we start mailing questionnaires.

Best wishes,



Dr Gareth Jones
Senior Lecturer in Epidemiology – University of Aberdeen

OVERVIEW

The primary objectives of SIRAS are to provide basic descriptive epidemiological data on the AS population in Scotland and Northern Ireland, and to establish an AS registry for the potential future studies of both aetiology and outcome.

As a brief reminder, SIRAS is being conducted in two “phases” and although Phase 1 started earlier, it will continue to run throughout Phase 2.

Phase 1 is an audit of the medical records of patients with ankylosing spondylitis currently seen in rheumatology clinics in Scotland / Northern Ireland. The aims of Phase 1 are:

1. To enumerate and characterise all patients with ankylosing spondylitis currently seen in

rheumatology clinics in Scotland / Northern Ireland;

2. To create a database of clinical information on the above patients, and to determine what information is currently recorded in clinical notes and whether this varies between centres.

Data is extracted from records by research nurses on to a paper data collection sheet. The data is then inputted on to a web-based database, held in Aberdeen.

Thus, Phase 1 involves no data to be collected directly from patients.

Phase 2, in contrast, involves the mail out of self-completion questionnaires to all patients with ankylosing spondylitis who have been seen in clinic within the past two years. Specifically, the aims of Phase 2 are to collect self-report measures of general health, pain, fatigue and

quality of life. Also – and crucially – we will be requesting consent to link the Phase 2 questionnaire data with the clinical information from Phase 1.

PHASE 1

West of Scotland

After a few “test” centres at the end of 2008, recruitment has been ongoing properly since February 2009. A number of nurses, based at the University of Glasgow Clinical Research Facility (CRF) are collecting data from several hospitals in the Glasgow / Clyde area:

- Glasgow Royal Infirmary
- Gartnavel General Hospital
- Stobhill General Hospital; and
- Inverclyde Royal Hospital.

To date, clinical information from 191 patients has been collected.

Recruitment is ongoing in these hospitals and we are currently in discussion with the Clinical Research Facility about capacity to expand recruitment to other hospitals in the West of Scotland.

North of Scotland

Recruitment has been ongoing since April 2009, with a nurse from the University of Aberdeen CRF. To date, clinical information from around 90 patients, all from Aberdeen Royal Infirmary has been collected.

Recruitment in the North of Scotland has been slower than hoped, due to the departure of both the Study Coordinator, Joy Hay, and the research nurse. We are currently re-advertising for both

positions but, meanwhile, have put in place a number of temporary measures over the summer, to allow recruitment to continue. In addition, we have recently approached Inverness and Fife about starting data collection in these areas.

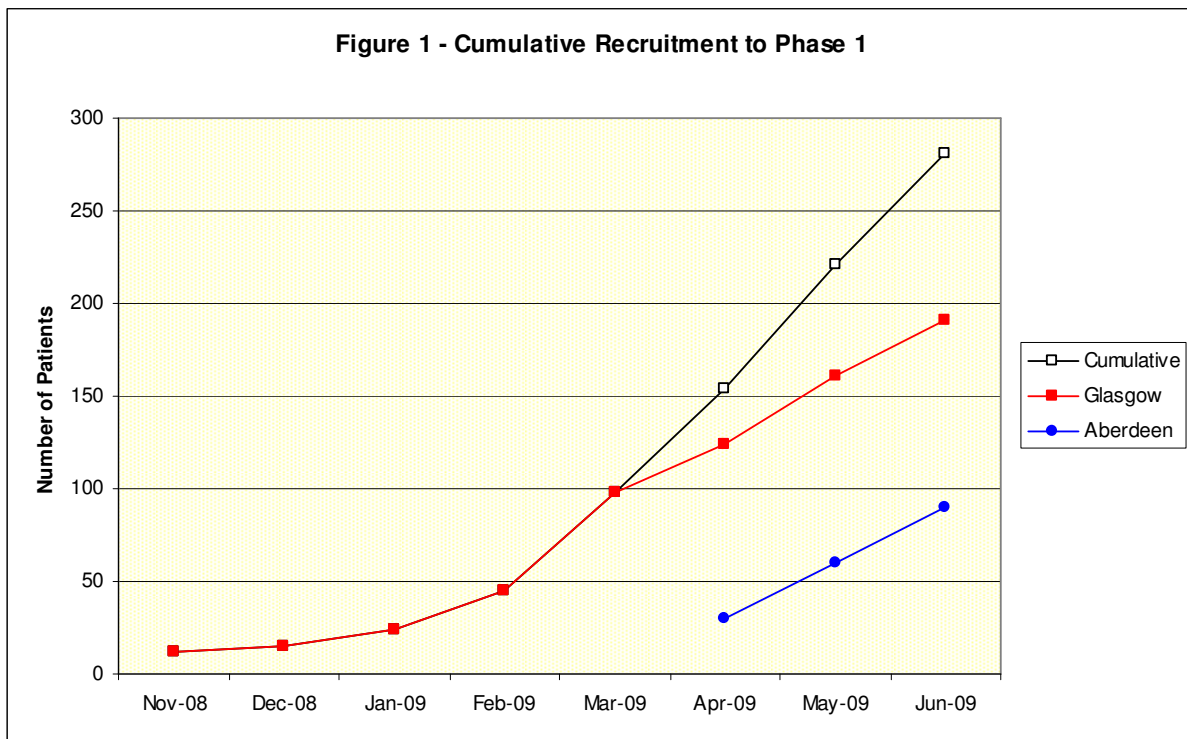
East of Scotland

After a very positive meeting with the Lothian Ankylosing Spondylitis Group in mid-June (many thanks to Mike Lambert, and to Wyeth) we hope to start recruiting from Lothian in late July and are currently in negotiation with the Wellcome Trust Clinical Research Facility about the logistics of this.

Overall

Overall recruitment is shown below in Figure 1. In brief, recruitment has been climbing steadily since data collection started, inevitably boosted by Aberdeen coming on board in April.

Some, but not all, of the data has been entered on to the database. Initially, only a small number of questionnaires were entered, to allow us to identify any teething issues. These have been identified, and rectified, and data entry is now continuing. However, contrary to the original plan, we have brought all completed data extraction sheets to Aberdeen and are undertaking all data entry centrally, to allow the research nurses to spend more of their time collecting data.



July 2009 figures not yet incorporated.

PHASE 2

Ethics approval for Phase 2 – the collection of self-report data – was granted earlier in the year. Absence of a study coordinator in Aberdeen, combined with the restructuring of R&D approval in Scotland, to one NRS Coordinating Centre (NRSCC), has delayed R&D approval for the study.

In addition, we are trying to get approval for the whole of Scotland and Northern Ireland simultaneously which has led to a number of complications with NRSCC. However, we are now in fairly advanced discussions with them and we hope to have approval shortly.

We are planning to send questionnaires to patients on a clinic-by-clinic basis, starting with Inverclyde, and are in discussions with the West of Scotland nurses (who are servicing Inverclyde for Phase 1) about the logistics of this.

We hope to send the first wave of questionnaires by the end of July. Thereafter, pending R&D approval, we will coordinate questionnaire mailings with other clinics as and when is mutually convenient.

FUTURE USE OF SIRAS DATABASE

SIRAS will only be successful as a research resource if people use it. There are a number of

models for potential research studies using the SIRAS data:

- Secondary analysis of data already collected;
- Secondary analysis of existing data, augmented by additional material – e.g. x-rays; or
- Ad hoc mail out to participants (all participants of Phase 2 are asked to give their consent to be approached for further research).

We have already been approached by a number of interested parties and are currently formalising

the procedures for data access, and issues such as authorship. However, as data collection continues, there will be a wealth of data available and we encourage applications for use of the data.

Please contact siras@abdn.ac.uk in the first instance.

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Wyeth

 **Abbott**
A Promise for Life