ESOS European Scleroderma Observational Study: treatment outcome in early diffuse cutaneous systemic sclerosis (SSc)

This is a prospective, observational study comparing the effectiveness of currently used immunosuppressant treatments for early diffuse cutaneous systemic sclerosis.

Who is eligible?

Participants are eligible if:

- They have diffuse cutaneous SSc with skin thickening of < 3 years
- They are aged > 18 years
- Able and willing to conform with one of the following treatment protocols: mycophenolate mofetil (MMF), methotrexate, cyclophosphamide or 'no immunosuppressant treatment'.

Participants are ineligible if:

- They have previously received stem cell transplantation
- They have received > 4 months of immunosuppressant treatment (including methotrexate, MMF or cyclophosphamide)
- They have received an immunosuppressant treatment (other than methotrexate, MMF or cyclophosphamide) in the previous 1 month.

What is involved for the clinician?

- Following informed written consent by a patient, we ask clinicians or support staff to log on to a protected web-based data collection system (http://www.ssc-esos.net)
- Complete a short eligibility checklist and a baseline questionnaire. This will take approximately 20-30 minutes.
- Complete follow-up forms which will appear on the system at regular time-points.
- Collecting routine clinical data, as set out in the table below.

	Visit 1 0 month (Baseline)	Visit 2 3 month	Visit 3 6 month	Visit 4 9 month	Visit 5 12 month	Visit 6 15 month	Visit 7 18 month	Visit 8 21 month	Visit 9 24 month
Confirmation of treatment choice and any changes	x	x	x	x	x	x	x	x	x
Modified Rodnan skin score	x	x	x	x	x	x	x	x	x
Yes/no checklist of internal organ involvement	x	x	x	x	x	x	x	x	x
Haemoglobin, ESR, plasma creatinine, eGFR, CRP, urinary dipstix results	x	x	x	x	x	x	x	x	x
FVC, TLCO results	x				x				x
Estimated PAP results	x				x				x
Set of participant questionnaires	x				x				x

What is involved for the clinician?

- There will be a set of questionnaires for patients to complete in clinic at 3 visits: baseline, 12 and 24 months. These are provided in the appropriate language and have completion instructions attached.

Support available

There is a full-time study coordinator based in the UK to assist with the study.

Costs

We are able to offer a payment of 312 Euros per participant in exchange for your time and effort. Half will be paid after the baseline form is submitted and the other half is paid after the participant has finished the study.