Letter to patient associations

Planning a family and wishing for children ?

Are you a patient with systemic sclerosis who plans a pregnancy for the years 2013-16? Or are you a patient already pregnant? Perhaps you are interested to participate in our international observational prospective study initiated by EUSTAR on pregnancy in women with systemic sclerosis: **IMPRESS 2 Study: International Multicentric prospective study on PREgnancy in Systemic Sclerosis**.

Why are we doing a study like this?

Systemic sclerosis (Scleroderma) occurs much more frequently in women than in men. The mean age at onset of symptoms is in the early 40's. Therefore, women have the potential to become pregnant after the onset of the disease. Since only few studies have included large numbers of pregnant patients and followed them before during and after pregnancy, a number of important questions remain open and need more extensive study. Among them:

- Does pregnancy alter the course of systemic sclerosis in the short term or long term?
- Are different forms systemic sclerosis differently influenced by pregnancy?
- Does systemic sclerosis increase the risk of pregnancy complications?
- What are the prospects of patients with renal disease, heart or lung disease to deliver a term, healthy child?
- Are complications of SSc more frequent during pregnancy than in the non-pregnant state?
- What is the best treatment for complications of systemic sclerosis during pregnancy?
- How should systemic sclerosis be monitored during pregnancy?

To answer these important questions requires a study of the disease course both in pregnant patients and in age-matched non-pregnant patients with systemic sclerosis over a period of 2 years. Ideally, one hundred pregnancies of scleroderma patients should be included, and one hundred non-pregnant scleroderma female patients should be monitored in parallel. As a control for the pregnant patients with systemic sclerosis, healthy pregnant women will be followed during their pregnancies as well.

The study design is as follows:

Pregnant SSc patients:

They are the cases and are studied before (already when planning a pregnancy), during and after pregnancy. Data are collected at these time points: once before pregnancy, once in the 1st trimester, second and third trimester, more often if disease activity requires it; at delivery and then 1 year after delivery or at time of a flare. However, a pregnant scleroderma patient can be included any time during her pregnancy!

Non-pregnant SSc patients 20-45 years old: these constitute the controls for the pregnant SSc patients and will finally be matched for age and disease type with the pregnant patients. They also represent a pool of SSc women who may become pregnant in the future.
Non-pregnant SSc patients show the disease course over a period of 2 years with complications of disease and adjustments of therapy. This can answer the question: are disease complications more or less frequent during pregnancy?

Healthy pregnant women: They are studied at the same time points of pregnancy as the pregnant SSc patients. They show the physiological changes of pregnancy both in laboratory and in clinical symptoms. These can then be separated from disease related changes/events.

Duration of the study
2 years

Storage of serum samples
At each visit serum samples might be taken (only with the agreement of the individual) from all patients and controls according to local practices. These samples are assessed for markers of disease activity and disease type and will also serve for studies of new antibodies, cytokines or proteins of interest in systemic sclerosis.

Importance of the study
An international project including European and American centers will provide sufficiently large numbers of patients to study pregnancy in this rare disease. By including two control groups, comparisons can be made between SSc pregnant and healthy pregnant women as well as between pregnant SSc patients and non-pregnant SSc patients. The latter comparison can detect whether pregnancy has a major influence on disease activity and prognosis of SSc. In addition, the project allows to find out whether subsets of SSc show different complications of pregnancy or of pregnancy outcome and child health. The study will help to find the best way to monitor pregnant patients with systemic sclerosis, to treat arising complications during pregnancy and to ensure a healthy pregnancy for mother and

child. Furthermore, the results will improve counselling of patients with systemic sclerosis who plan a pregnancy.

Publication

The results of the study will be published in Medical Journals and will also be summarized in special articles for Scleroderma Patient Associations.

Patient involvement

Women .who want to participate in the study should .notify their doctors. Please, note that we want to include both patients who plan a pregnancy, patients who are pregnant and scleroderma women aged between 20-45 years. If the center in which the patient .is monitored is already included in the IMPRESS network, it should be easy to collect all clinical data. If the center in which a patient is followed is not yet included in the IMPRESS 2 network, we will be happy to include that new center. However, any individual patient may contact directly the main European investigators to arrange the easiest way to collect and record her own clinical data In case the local center does not have the time or the possibility or even the interest in collecting the data, the main organizing centers may help the local center. Our aim is that each pregnancy occurring in a scleroderma women in Europe should be offered the possibility to be included in the IMPRESS 2 project, since we anticipate that the results of IMPRESS 2 study will be important for all the Scleroderma women contemplating a possible pregnancy.

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