Information notice

International Registry of Severe Cutaneous Adverse Reactions (SCAR) to Drugs and Collection of Biological Samples (RegiSCAR)

Doctor (1), asked me to participate in a biomedical research entitled "International Registry of Severe Cutaneous Adverse Reactions (SCAR) to Drugs and Collection of Biological Samples (RegiSCAR)". This study has contracted an insurrance according to the laws on biomedical research. The physician specified that I have the freedom to accept or to deny my participation in this research.

To help me making up my mind, I have been given the following information.

Every medication may induce an adverse reaction. The most serious reactions are very rare but need a special interest for a good evaluation of the risks of treatments. Present knowledge is insufficient on the mechanisms of severe cutaneous adverse reactions (SCAR) to drugs and on their potential long-term effects on the daily life of persons who experienced such acute reactions.

The aims of the research are

1) to quantify the level of risk of several SCAR (Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), hypersensitivity syndrome/drug reaction with eosinophilia and systemic symptoms (HSS/DRESS), acute generalized exanthematous pustulosis (AGEP)) for every drug likely to induce these diseases,

2) to constitute a « bank » of blood samples from patients suffering from these diseases in order to study the mechanisms of such adverse reactions to drugs and to look for genetic factors that may increase the risk of reactions,

3) to follow up if indicated a cohort of patients for evaluating the risk of sequelae..

Because these diseases are very rare the research will be conducted in several countries.

Expected benefits for participants are:

1) A better chance to find out which drug has caused the reaction from interview with a specialised investigator,
2) If indicated, a follow-up examination after discharge from the hospital will allow to detect and to treat any sequelae.

Constraints and risks are

1) the burden of the initial questionnaire that will last about 30 minutes,
2) the time for the follow-up examinations and questionnaires if indicated (30 to 60 minutes),

3) sampling of blood and skin. A sample of 60 ml of blood (30-40 for children), i.e. about one tenth of a blood donation, will be drawn in addition to the quantity of blood drawn for examinations needed for the management of the disease. A fragment of the skin biopsy necessary for the diagnosis will be used for research without an additional biopsy.

Samples will be drawn before the 6th day of hospitalisation. The questionnaire will be administered before I leave the hospital.

The biological samples will be sent to a standardized « bank ». Serum, cells (lymphocytes) and genetic material (DNA) will be extracted from the blood, frozen and stored anonymously in this centre until redistributed to various scientists of this study group for the research already scheduled or for future research. Frozen samples will be kept for at least 10 years and will be used only for research on the mechanisms of cutaneous reactions to drugs. I will not have to pay in relation to these samples and will be free to require at any time the destruction of my samples. The samples will only be used for academic and not for any commercial background.

Physicians organising this research do not expect that the results will have a direct impact on my health, but rather a more general impact. For example, the discovery of a test that could predict the severe adverse reaction that I experienced would be very useful to protect other persons, including my relatives, but would not change anything for myself. Therefore, overall results will be released but not results on individual samples. If I wish so, I will be informed of these global results after the end of the study.

The results of the overall data obtained during the study may produce new diagnostic tests or new treatments that may result in patent(s). In such instance I will not claim any intellectual or financial property on this patent.

This research has been approved by the Ethical Committee of on (date).

Medical data on my disease, medical history, life habits and because of specific needs of this research on my ethnic origin will be computerised in agreement with national and international regulations. These data will remain confidential. I will be able to have an access to the data from Dr .

(1) Full name, address and telephone