„SDNTT“ - Swiss Dermatology Network for Targeted Therapies:

Patient information

Dear patient

1. Selection of study participants

You have been asked to participate in the psoriasis-registry SDNTT because you are receiving medical treatment for your psoriasis.

2. Goal

The study will include about 750 patients from Switzerland and monitor them for 10 years. This form of long-term data collecting is called “patient registry”. The goal of this registry project “SDNTT” is to examine the effectiveness of modern psoriasis therapy under everyday life circumstances, the benefits to the patients as well as the safety of the drugs. Patients who are about to start medical treatment with a biological agent or with a conventional systemic substance (for internal use) can participate in this study.

3. General information about the patient registry

Data about your course of treatment and possible side-effects will be collected and evaluated centrally for Switzerland. Since there are similar registries in Europe collecting similar data, these will be evaluated together. Therefore your treating doctor will ask you to fill out a questionnaire of several pages. In addition, your doctor will give us important information about your treatment.

This study will not affect your medical treatment. You will neither have to undergo any additional examination nor will you receive any other treatment than the one prescribed by your doctor.

4. Voluntary participation

Participation in this study is, of course, completely voluntary, and you will not suffer any disadvantages if you choose not to take part. You will also be able to withdraw your consent at any time without any explanation. This would not affect your further treatment in any way.

If you should decide to withdraw your consent, your personal data will be deleted and your disease-related data will only be used in an anonymized* form.

5. Study procedure

Participation in this study entails filling out a questionnaire today, in three and in six months, and from then onwards every six months (cf. figure 1). You will have to answer questions about your current medical condition, your state of health and possible side-effects of the drugs you have to take. You will receive your questionnaire from your dermatologist. The trial will last 10 years. Please give your name, address and phone number to the head office so that we can stay in contact even if you change your dermatologist.

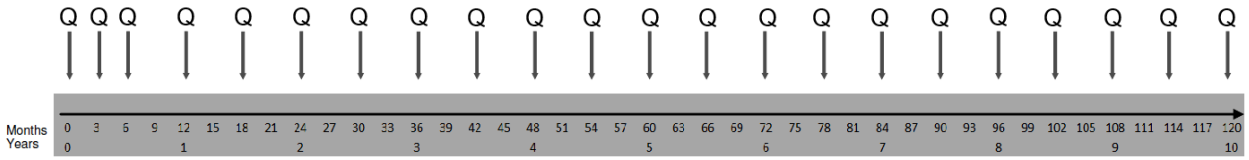

Figure 1: Questionnaires (Q) over a period of 10 years

6. Duties of participants

The study will not affect your medical treatment. Participation in the study will not involve any duties.

7. Benefits for participants

There is a strong need for additional information regarding the effectiveness of the therapies, the benefits to the patients and the safety of the drugs. This information can only be gathered if doctors and patients co-operate in long-term observation studies. It is for this reason that your treating doctor is participating in this study which is conducted by the Swiss Dermatology Network for Targeted Therapies (SDNTT) together with the German Center for Health Services Research in Dermatology (CVderm, Competenzzentrum Versorgungsforschung in der Dermatologie) at the University Hospital Hamburg.

8. Risks and discomforts

The study does not affect your medical treatment. All clinical trials have concluded that the drugs you have been prescribed are safe and well tolerated.

9. New findings

Your dermatologist will inform you of any new findings that could influence the benefit or safety of your therapy and thus your participation in the study. You will receive this information in written form.

10. Confidentiality of the data

All the personal and disease-related data which are collected in the course of the study will be subject to medical confidentiality and data protection laws. Your data will be forwarded by your treating doctor to a data security officer of the CVderm at the University Hospital Hamburg, where your data will be pseudonymized**. In Germany, the law on data protection is very similar to the Swiss law.

Staff members of CVderm may look at the medical records sent by your treating doctor for control purposes. That means that only your treating doctor and staff members of CVderm can connect your data to your person.

11. Costs
Participation in this study will not result in additional costs for you or your health insurance.

12. Compensation for participants
You will not receive any compensation for your participation.

13. Contacts

For further questions please contact the dermatologist on duty on: 079 336 78 66 or 022 372 33 11.

Thank you very much for your collaboration!

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Study Director
PD Dr. med. Emmanuel Laffitte

* Anonymization is the deletion of names and other identification details so that the identification of the person is impossible.
** Pseudomization is the replacement of names and other identification details with a code so that the identification of the person is very difficult if not impossible.