



**Departments of Dermatology and Immunology
Dessau Medical Center
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Malignant Atrophic Papulosis – Köhlmeier Degos disease

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Information for patients and relatives

Dear patients, dear relatives

Malignant Atrophic Papulosis is a very rare disease characterised by typical skin lesions. In addition to this, the disease can affect the blood vessels of the body; when the gastrointestinal or the central nervous system is affected it is a life-threatening condition. Until now, there has been little knowledge or understanding of the disease.

Aim of the study

Determination of the aetiology of the disease – attempt to determine whether a familial predisposition can be found by genetic examination and verification of the vessel involvement. No previous results/studies are available.

Procedure for and duration of participation

- One single withdrawal of blood (venous), 2 sodium heparin tubes (2x7-10 ml) + 2 tubes for routine biochemistry tests (2x7-10)
- 2 skin tissue extractions (from affected and clinically healthy skin) with punch biopsies (ie 2x6 mm diameter).
- Every sample will be processed and encoded with a secret number. The connection between the trial number and the name of the patient is known only to and available to the doctors involved in the study

Possible risk factors

Scarring, possible local infection, intolerance to local anaesthetic or nerve lesion.

Clarification

The study has the purpose of creating a Biobank of samples for genetic examinations, that will prove to be suitable in the near future, in order to search for the origin and eventually for a therapy for this disease (Morbus Köhlmeier-Degos)

The results of these examinations will be knowledge worthy only as cumulative and not as single cases.

Therefore, it is of no purpose to announce to you the results of these examinations made from your samples as single cases; please try to understand this. However, you are going to be informed about the results of research in general.

By signing the declaration of consent, you declare that you agree that the doctor in charge of the study and his colleagues may record and process data related to your person for the purposes of the above-mentioned study. Person-related data are, for example, your date of birth, your sex, your race or your ethnicity, data on your physical or mental health or other personal data, which are recorded during your participation in the study or during follow-up examinations. The doctor in charge of the study shall use data related to your person for the administration and execution of the study, as well as for research purposes and statistical evaluations.

The doctor in charge of the study shall release the study-related data gained during the project after the study is complete. The study-related data released to third parties shall no longer contain your name or your address. Instead, the doctor in charge of the study shall provide the study data with a code number (providing the data with a pseudonym). Only the doctors in charge of the study (Prof. Zouboulis und Dr. Theodoridis) have access to the cipher key, which allows the study-related data to be linked to you. The data stored as mentioned above shall be saved for a period of 10 years.

You retain the right to access information about all data which pertains to you and which is in the possession of the doctor in charge of the study or the party commissioning the study. You also retain the right to correct possible inaccuracies in your person-related data. If you would like to submit a query, please contact your doctor in charge of the study. The address and telephone number of the study doctor can be found at the end of this form.

Please note that the results of the study can be published in medical publications, whereby your identity nevertheless remains anonymous.

The blood and/or tissue samples extracted as part of the above-mentioned study shall also be encoded and shall be transferred in this form to the laboratory of the Departments of Dermatology and Immunology, Dessau Medical Center, Dessau for the purposes of the above-mentioned study. The samples shall be stored for a period of 10 years in the laboratory, after which they shall be destroyed.

You can refuse the further processing of your data within the above-mentioned study and/or all further research of the samples taken from you at all times and demand that they be deleted or destroyed.

No insurance policy has been concluded for you; only the doctor in charge of the study is insured by employers' liability insurance against liability claims, which could result from his culpable conduct.

You have the right, at all times, to question the study doctors about all matters, which have to do with the study, especially about the risks.

You have the right to refrain from participating in the study without providing a reason and without this infringing upon the medical measures which may otherwise be necessary for you. The same applies for abandonment of participation in the study and the retraction of consent for the further processing of your data.

Your contact partner is Prof. Dr. Med. Christos Zouboulis and Dr. Athanasios Theodoridis, Tel. +49-0340- 5014000 / 01.