Skånes universitetssjukhus

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Information to participants in a research study

We want to ask you to participate in a research project. In this document you get information about the project and what it means to participate.

What kind of project is it and why do you want me to participate?

Skin cancer is the fastest growing form of cancer in Sweden today. Making the right diagnosis early can reduce morbidity and save lives. However, diagnosing skin change using only eyeballing can be very difficult. To improve the diagnostic ability, there are various tools and applications. How they should be used in healthcare is, however, insufficiently studied and it is important to ensure that they are used in a safe and economically efficient manner. Our study will specifically examine the use of teledermatoscopy and artificial intelligence/ deep machine learning.

Dermatoscope is an instrument that provides a magnification and optimal lighting when examining skin changes, which increases diagnostic accuracy. In teledermatoscopy, dermatoscopic images, taken in primary care, are assessed by a dermatologist at a distance. Diagnostic algorithms, for example algorithms constructed using artificial intelligence, can then be used as an aid in the assessment. With our study, we want to investigate how well teledermatoscopy and diagnostic algorithms work in clinical practice.

Because you are seeking medical care for a skin change, you are asked to participate in the study.

The responsible research organization is Region Skåne in close collaboration with Lund University and the Stockholm-Gotland Region in collaboration with Karolinska University Hospital. The responsible research organization means the organization that is responsible for the study.

How is the study done?

As a participant (research person) in this study, you give us permission to photograph your skin change and obtain brief information about you. This only takes a few minutes. Then you get exactly the same care as if you were not included in the study. This may mean that in addition to the photography, you also need an assessment at a skin clinic, sampling with a biopsy or surgery or renewed imaging after a few months.

Possible consequences and risks of participating in the study

In this study, we work mainly with processing images, which will not involve any risk to your health. Participation in the study does not include any further sampling, other than those included in the usual investigation of your skin change.

We strive to take pictures in a way that prevents you from being identified in the picture. If images cannot be made unidentifiable by cropping or retouching, they will be removed from the study.

What happens to my information?

The project will collect information about you in order to conduct research. When a teledermatoscopic referral has been created with attached images, all information is sent to one of Region Skåne's or Region Stockholm-Gotland's servers. The information will then become a journal document and stored as such. No information or images remain in the smartphone, it is only used as a tool for collecting information. Information about you will also be obtained from your medical record, e.g. the result from the microscopic assessment of a skin sample, information about any previous skin diseases or additional images of skin changes stored in the healthcare image management system. We will also link your data to national registers regarding the incidence of skin cancer. All information is gathered in a protected electronic research database, to which only authorized personnel have access.

When image analyzes are to be carried out, data is extracted from the server where the images are saved to a research database. In this step, all personal data will be removed and each case will receive a unique code. The code is used if a research person wishes to receive an extract of their data or wishes to be removed from the research database. The research database is only accessible to participating researchers in this study and is stored on highly secure password-protected servers belonging to Lund University or Region Skåne. The research database will be saved 10 years after the studies have been published, according to the Archives Act (1990:782).

Responsible for your personal data is Region Skåne, Skåne University Hospital and Region Stockholm-Gotland, Karolinska University Hospital. The processing of data follows the European Union's "general data protection regulation (GDPR)" through the legal bases "agreement with you who will be registered in the research database" and "handling of data in the public interest". According to the GDPR, you have the right to get an extract of the information gathered about you free of charge, and, if necessary, to have any errors corrected. You can also request that information about you be deleted and that the processing of your personal data be restricted. If you want to proceed with any of these measures, please contact: Åsa Ingvar, Dermatology Department, Skåne University Hospital, Lasarettsgatan 15, 221 85 Lund, email: teleforskning.hud.sus@skane.se , phone number 046-172113. The Data Protection Officers can be contacted at the following addresses: Region Skåne, 291 89 Kristianstad, 044-3093000 and Karolinska University Hospital: Data Protection Officer, 171 76 Stockholm, 08-58580000. If you are dissatisfied with the way your personal data is processed, you have the right to file a complaint with the Swedish Authority for Privacy Protection (Integritetsskyddsmyndigheten), which is the supervisory authority.

How do I get information about the study results?

When the studies are completed, research reports will be written and published in international peer-reviewed scientific journals. If you have not been informed of the outcome of your teledermatoscopic or clinical examination, you can contact the healthcare facility where it was performed.

Insurance and compensation

As with regular healthcare, you are entitled to compensation for injuries or malpractice even when you participate as a research person in this study. This is regulated by the Patient Injuries Act and patient insurance is taken out by all Sweden's regions with ”Landstingens ömsesidiga försäkringsbolag (LÖF)”. For more information see https://lof.se/.

Participation is voluntary

Your participation is voluntary and you can choose to cancel your participation at any time. If you choose not to participate or want to cancel your participation, you do not have to state why, nor will it affect your future care or treatment.

If you wish to cancel your participation, please contact the person responsible for the study (see below).

Responsible for the study

Responsible for the study is Åsa Ingvar, Hudmottagningen Skånes Universitetssjukhus, Lasarettsgatan 15, 22185 Lund. Email: teleforskning.hud.sus@skane.se . Phone number: 046-172113.

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Consent to participate in the study

I have received written and digital or oral information about the study, have understood that I can ask questions and who I should then contact. I may keep the written information on paper or as a downloaded PDF document.

- I agree to participate in the study "Teledermoscopy and artificial intelligence: implementation in healthcare and development of clinically relevant applications"

- I agree that information about me is processed in the manner described in this research person's information.

Place and date	Signature and name in printing