IDS Study Proposal

Dermoscopy of skin of color

Version 1.0

Date: 2018-11-13

Principal Investigator: Ralph Braun
e-mail: ralph.braun@usz.ch

Study Coordinator: Ashfaq Marghoob
e-mail: marghooa@mskcc.org

Proposed start date: 01.01.2019
Proposed end date: 01.01.2020

Conflict of interest

Non

Funding Sources

none

Financial or personal interest related to the proposed study

none

Interest in intellectual property rights subject of the study

none

Is a drug, device or other investigational product being used or evaluated?

No

Study design

Study type

Retrospective web based cohort study, including a prospective data collection

Checklist

none

Study Outline

Dermoscopy is widely used for the diagnosis of skin lesions but only little is known about dermoscopy of skin of color. We know that the dermoscopy criteria vary with localization, age and skin type. We know as well that dermoscopy criteria of skin of color are different and have to be interpreted in the context of the skin type.

Objective:
To describe the dermoscopy criteria of nevi, melanoma and other entities in skin of color

Methods:
Members of the IDS will be invited to submit any cases of histologically confirmed lesions on skin of color. High quality dermoscopy images as well as some clinically relevant information (localization, Skin type, age etc.) will be required.

A standardized assessment of the clinical and dermoscopy images will be performed by a central group of investigators who will be blinded to the diagnosis (RB; AM; JM; MM etc).

Duration of image information and collection:
The study is retrospective and the collection will be performed as long as we have enough cases according to the statistical evaluation.

For every participating center we will provide an excel sheet in order to fill out the requested information.

Recorded data

Dermoscopy image, Histology diagnosis, Clinical information such as Skin type, localization, sun exposed area etc.

Methodology of data collection

For every participating center we will provide an excel sheet in order to fill out the requested information.

Statistical evaluation plan

The statistical evaluation is going to be done by Steve Dusza (MSKCC). As soon as the protocol is accepted, we will have Steve draft the statistical analysis and to calculate the number of cases needed for this study.

Ethics

Central ethics review already in place?

This type of study does not require ethics approval but a waiver from the ethics committee according to the swiss law on research in humans

Informed Consent Form

We will only include images on which the patient is not recognizable. If the local law required a consent form, this will be in the responsibility of the contributing center

Ethics and Data security considerations

The data will be transferred anonymously and the clinical data will be strictly anonymous. This being said there is no ethical or security concern.

Authorship and compensation

Criteria for co-authorship

Contributing at least 10 cases

Criteria for named contribution

none

Other compensations planned

none

Accessibility of results

Results will be published

Data availability after publication

We will make the data available on request

Resources

Requested resources from the IDS

Presentation on the Study site and promotion of the study