IDS Study Proposal

Dermoscopy of porokeratosis

Version 1.0

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Proposed start date: March 10, 2019
Proposed end date: June 30, 2019

Conflict of interest

Funding Sources

Not applicable

Financial or personal interest related to the proposed study

None

Interest in intellectual property rights subject of the study

Not applicable

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

No

Study design

Study type

Retrospective Cohort

Checklist

Not applicable

Study Outline

The study aims to describe the dermoscopic features of porokeratosis. In order to collect a higher number of cases than what is feasible from a single center, an international collaboration is desirable and the IDS is a good platform for this.

The study design will be a retrospective cohort study. IDS members are welcome to participate in the study by sharing clinical and dermoscopic images of histopathologically confirmed cases of porokeratosis to the study coordinator. All the images will be evaluated by a local group of experts in dermoscopy in order to describe the dermatoscopic features that are present.

Inclusion criteria for submitted cases:
- high quality macroscopic and dermoscopic **images*** of the porokeratosis lesion.
- histopathological confirmation of a porokeratosis diagnosis (histopathological image is optional).
- whether the images represent a single porokeratosis of Mibelli or disseminated superficial actinic porokeratosis.
- demographic and clinical data: patient's sex and age at diagnosis as well as the lesion's location and size.

* **All images should be de-identified** prior to submission.

There is no primary hypothesis of this study, since the aim is solely to describe dermatoscopic features of porokeratosis. Until now, only case reports and small case series regarding the dermoscopic features of porokeratosis have been published.

Recorded data

Dermoscopic and macroscopic images and limited anonymized demographic/clinical data from the patients.

Methodology of data collection

Images matching the inclusion criteria can be sent to to the principal investigator or study coordinator via e-mail:
- john.paoli@vgregion.se
- oscar.zaar@vgregion.se

Statistical evaluation plan

Standard descriptive statistics will be used to describe the data with categorical data summarized as number and percentage of the population, continuous variables with a normal distribution as the mean ± standard deviation and continuous variables with a non-normal distribution as the median ± interquartile range. A consensus on the dermoscopic features of each lesion will be performed by experts in dermoscopy following initial individual assessments. Kappa values will be calculated using Fleiss' test when studying interobserver concordance for more than two observers. The specific traits will be summarized in a table organized in frequency of the trait for all collected cases of porokeratosis.

Ethics

Central ethics review already in place?

An ethics review is in place and the study has been approved by the Ethical Review Board of Gothenburg.

Informed Consent Form

Not applicable as long as the cases are de-identified.

Ethics and Data security considerations

Not applicable as long as the cases are de-identified.

Authorship and compensation

Criteria for co-authorship

Providing at least 5 cases.

Criteria for named contribution

Providing at least 1 case.

Other compensations planned

Not applicable

Accessibility of results

The study will be published in an open access journal.

Data availability after publication

Data will be available for other research groups after conclusion of the study upon request.

Resources

Requested resources from the IDS

Notification to all IDS members through the IDS mailing list and linking from the IDS website in order to promote the study. Promotion through the IDS social media channels would also be appreciated.