

Trial Description

Title

Training and validation of an automated diagnostic deep learning algorithm in dermoscopy

Trial Acronym

AD-LEARN DERMOSCOPY study

URL of the trial

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Brief Summary in Lay Language

Non-invasive, retrospective analysis of available, beforehand generated digital images for evaluation of a computer software in comparison to conventional physicians' evaluation of dermoscopic pictures of nevi and melanoma.

Brief Summary in Scientific Language

In this retrospective non-interventionell study the analysis of digital dermoscopic images of pigmented skin lesions (nevi and melanoma) by multiple physicians will be compared to analysis of the images by a trained deep-learning-algorithm.

Organizational Data

- DRKS-ID: **DRKS00013570**
- Date of Registration in DRKS: **2017/12/14**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-629/2017 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1206-3791**

Health condition or Problem studied

- ICD10: **C43.9 - Malignant neoplasm: Malignant melanoma of skin, unspecified**
- ICD10: **D22.9 - Melanocytic naevi, unspecified**

Interventions/Observational Groups

- Arm 1: **In this study a retrospective analysis of available, beforehand generated digital images for evaluation of a computer software in comparison to conventional physicians' evaluation of dermoscopic pictures of nevi and melanoma will be performed.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Objective of this retrospective analysis is the assessment of the diagnostic performance of a computer algorithm in analyzing dermoscopic images in comparison to dermatologists. Diagnostic Performance will be assessed by means of sensitivity and specificity. Estimated study Duration is 12 months.

Secondary Outcome

There are no secondary objectives in this study

Countries of recruitment

- DE **Germany**

Locations of Recruitment



- University Medical Center **Hautklinik, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/16**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **120 Years**

Additional Inclusion Criteria

Patients with dermoscopic images depicting nevi or melanoma

Exclusion criteria

Low Image quality

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

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Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

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Deutsches Register
Klinischer Studien

German Clinical
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* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*