Clinical validation study of a CAD system with artificial intelligence algorithms for early non-invasive detection of in vivo cutaneous melanoma. (LEGIT_MC_EVCDAO_2019)

First published: 03/01/2024

Last updated: 01/07/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS108254

Study ID

108436

DARWIN EU® study

No

Study countries

Spain

Study description

The SARS-CoV-2 pandemic poses challenges to global healthcare systems, impacting the care of COVID-19 patients and causing disruptions in various medical disciplines, including dermatology.

Urgent measures, initiated almost two years ago, aimed to prioritize COVID-19 cases, resulting in a backlog of non-urgent consultations.

Dermatology practices were considered potential vectors of COVID-19 transmission, leading to the suspension of non-urgent consultations.

The ongoing threat from evolving virus variants has hindered the restoration of normal healthcare flows. In response, an alternative system is imperative for efficient and timely diagnosis and remote patient monitoring. The imbalance in dermatologist-to-patient ratios, especially in Spain and other European countries, accentuates the need for such a system.

Delayed diagnosis of skin conditions, including potentially life-threatening melanoma, and exacerbation of chronic diseases during the pandemic underscore the urgency.

Currently, no reliable tools exist for remote pathology diagnosis, emphasizing the importance of implementing an innovative solution. Human limitations in quantifying parameters and inherent biases in patient-reported measurement scales further impede accurate assessments.

The inadequacy of existing methods, coupled with the reluctance of patients to seek in-person consultations during the pandemic, highlights the necessity for advanced diagnostic tools. The study advocates for the clinical validation of an artificial intelligence tool, Legit.Health, designed to grade disease activity in dermatological patients.

Artificial intelligence, particularly Computer Aided Diagnosis (CAD) systems, offers a promising avenue. These systems, leveraging artificial intelligence and image processing, enhance the interpretation of medical images, demonstrating competence comparable to medical experts.

Study status

Finalised

Research institutions and networks

Institutions

AI Labs Group S.L. (Legit.Health)

Spain

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Institution | Non-Pharmaceutical company | Other

Contact details

Study institution contact

Jesús Gardeazabal-García

jesus.gardeazabalgarcia@osakidetza.eus

Study contact

jesus.gardeazabalgarcia@osakidetza.eus

Primary lead investigator

Jesús Gardeazabal-García 0000-0001-5938-0835

Primary lead investigator

ORCID number:

0000-0001-5938-0835

Study timelines

Date when funding contract was signed
Planned: 04/11/2019

Actual: 04/11/2019

Study start date
Planned: 17/09/2020

Actual: 17/09/2020

Date of interim report, if expected
Planned: 17/10/2023

Actual: 23/10/2023

Date of final study report
Planned: 17/10/2023

Actual: 23/10/2023

Sources of funding

- National competent authority (NCAs)

More details on funding

Government institutional research programme

Study protocol

LEGIT_MC_EVCDAO_2019 Protocol v3.0 28102021_Melanoma_EN.docx-2d034302d0d9ac7f987c4ec35eb9b990.pdf (2.43 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

NCT06221397

https://register.clinicaltrials.gov/prs/beta/studies/S000E2DU00000030/recordSum...

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Study design:

The goal of this Cross-sectional analytical observational study of clinical case series is to validate a Computer-aided diagnosis software developed by AI Labs Group for the identification of cutaneous melanoma in images of lesions taken with a dermatoscopic camera.

Main study objective:

This study aims to validate our CAD system's capability, utilizing machine vision, for the early and non-invasive in-vivo diagnosis of cutaneous melanoma. The primary objective is to confirm that the AI algorithm developed for identifying cutaneous melanoma in dermatoscopic images achieves: AUC > 0.8 Sensitivity ≥ 80% Specificity ≥ 70%

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Additional medical condition(s)

Any kind of melanoma

Population studied

Short description of the study population

Patients with skin lesions with suspected malignancy seen at the Dermatology Department of the Hospital Universitario Cruces and Hospital Universitario Basurto.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

200

Study design details

Outcomes

Skin Lesion Recognition:
Top-1 Image-Level Accuracy: 52.86% (initial) / 48.25% (initial + extension).
Top-3 Image-Level Accuracy: 81.20% (initial) / 74.74% (initial + extension).
Top-5 Image-Level Accuracy: 88.83% (initial) / 83.16% (initial + extension).
Malignancy Prediction: AUC for Malignancy: 87.28% (initial) / 88.26% (initial + extension).
Adverse Events and Adverse Reactions to the Product: No adverse events or reactions related to the investigated device were observed.
Product Deficiencies: No deficiencies in the device were observed, it demonstrated consistent performance. Subgroup Analysis for Special Populations: No special population subgroups were identified in the context of the analyzed pathologies.

Data analysis plan

For the purpose of estimating the device's performance, we use different metrics depending on the task: Melanoma detection: Top-K precision Top-K sensitivity, Top-K specifity, AUC Malignancy prediction: AUC Skin lesion recognition: Top-K accuracy For this study, we set the value of K to 1, 3, and 5.

Documents

Study results

Study results_EUPAS108254.pdf (136.06 KB)

Study, other information

CEIM_LEGIT_MC_EVCDAO_2019 Modificacion FavorablePIB-5737d3c2e56f73d97a641783577c20ac.pdf (286.15 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Spontaneous reports of suspected adverse drug reactions

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown