Pilot study for the clinical validation of an artificial intelligence algorithm to optimize the appropriateness of dermatology referrals. (LEGIT.HEALTH_DAO_Derivation_O_2022)

First published: 03/01/2024

Last updated: 01/07/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS108167

Study ID

108432

DARWIN EU® study

No

Study countries

Spain

Study description

This study addresses challenges in primary care related to skin disease diagnosis. Discordant diagnoses between primary care physicians and dermatologists are common, exacerbated by a shortage of dermatologists, particularly in less populous areas.

The reliance on patient self-reporting introduces potential bias. To overcome these challenges, the study proposes the use of Computer-Aided Diagnosis (CAD) systems, leveraging artificial intelligence for image interpretation and classification. The primary aim is to clinically validate a software designed by Legit.Health for grading disease activity in patients. The objective is to enhance the reliability and precision of skin disease assessment and referral criteria.

The ultimate goal is to bridge the gap in dermatological care between primary care providers and specialized dermatology services, leading to improved patient outcomes. The study focuses on adult patients (≥ 18 years) with skin pathologies in the primary care service of health centers referring to Cruces and Basurto University Hospitals.

It adopts a prospective observational analytical study design of a longitudinal clinical case series. The specified number of subjects for the study is 400. However, as of the report, only 51 patients have been recruited from various health centers.

The initiation date was April 7th, 2022, and the completion date is pending, with an estimated duration of 4 months. This includes 2 months for recruitment, 1 month for specialist photo review, and 1 month for data analysis.

The study will remain active until the specified number of recruited patients is reached.

The primary objective is to validate the device as a tool for improving the adequacy of referrals to dermatology. Secondary objectives include validating the device's impact on reducing costs in secondary care, decreasing dermatology waiting lists, and optimizing clinical flow in Osakidetza.

Study status

Ongoing

Research institutions and networks

Institutions

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

Spain

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Institution | Non-Pharmaceutical company | Other

Contact details

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Study timelines

Date when funding contract was signed
Planned: 02/02/2022

Actual: 02/02/2022

Study start date
Planned: 07/04/2022

Actual: 07/04/2022

Data analysis start date
Planned: 07/07/2022

Actual: 23/10/2023

Date of interim report, if expected
Planned: 07/07/2022

Actual: 23/10/2023

Date of final study report
Planned: 15/10/2024

Sources of funding

- National competent authority (NCAs)
- Other

More details on funding

Medtech Initiative from the Basque Government

Study protocol

LEGIT.HEALTH_DAO_Protocol_Derivation_O_2022 v_2_0_EN-7346a43466f324337201eedc879a759f.pdf (2.97 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

NCT06228014

https://www.biocrucesbizkaia.org/servicios/medtech

https://register.clinicaltrials.gov/prs/beta/studies/S000E32O00000027/recordSum...

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Medical device

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Feasibility analysis

Healthcare resource utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a prospective observational analytical study of a longitudinal clinical case series. The study does not involve an active or control group, as it is focused on the evaluation of the device in a real-world clinical setting.

Main study objective:

To validate that the device developed by Legit.Health is a valid tool for improving the adequacy of referrals to dermatology and reduces costs in secondary care.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Population studied

Short description of the study population

Adult patients (≥ 18 years) with skin pathologies seen in the primary care service of health centers referring to Cruces and Basurto University Hospitals.

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

400

Study design details

Outcomes

We collected a total of 82 images from 51 patients using smartphones and dermatoscopes.
Patients with pigmented lesions tend to have more images on average because they include both clinical and dermatoscopic pictures.
The use of the device on the collected images lead to both a high sensitivity (100%) and specificity (76%) for the malignancy detection task.
Analysis of Teledermatology Cases: Dermatologists opted for in-person consultations in 71% of cases. 29% of cases were addressed directly, with 53% related to seborrheic keratosis. Performance on Low-Quality Images: Sensitivity on low-quality images: 100%, specificity: approximately 63%. Cost reduction potential by avoiding unnecessary consultations based on algorithm outcomes.

Data analysis plan

Each variable will be characterized using frequency distributions for qualitative variables and central tendency statistics such as mean and median and variability statistics such as standard deviation (S.D.) or interquartile range for quantitative variables according to their distributional characteristics.
Sensitivity, specificity, positive and negative predictive values (PPV and NPV) and likelihood ratios (LR+ and LR-) will be calculated by comparing both the results obtained using the device and those obtained with the referral criteria of primary care physicians with the criteria used by specialists, considered the gold standard.
Analyses will be performed using appropriate statistical software, SPSS version 23.0 and STATA 13.0. Values of $p<0.05$ will be considered significant.

Documents

Study, other information

CEIm_LEGIT.HEALTH_DAO_Derivación_PS2022074-5abceddcca6112d4daba41ad6bcb3309.pdf (341.77 KB)

https://www.biocrucesbizkaia.org/servicios/medtech

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No