Study for the clinical validation of a medical device for prioritising follow-up visits in patients at risk of melanoma (CVCSD_VC_2402)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000652

Study ID

1000000652

DARWIN EU® study

No

Study countries

Spain

Study description

With over 1.5 million new cases in 2020, skin cancers are among the world's most prevalent malignancies. Melanoma alone accounted for roughly 325,000 of these cases, and its incidence has climbed—especially in fair-skinned populations—due largely to increased UV exposure.
Although melanoma risk increases with age, it remains common in younger adults.

In Spain, a shortage of dermatologists—just three per 100,000 inhabitants—creates lengthy waits for specialist appointments (averaging 133 days in Catalonia and 63 days at leading centres), delaying diagnosis and worsening outcomes.
Up to 20% of GP referrals to dermatology are for benign lesions (e.g., seborrhoeic keratoses), further burdening services.

Teledermatology has eased some pressures but still struggles to prioritise high-risk cases efficiently.
Artificial intelligence offers a solution: computer-aided diagnostic algorithms can rapidly analyse images, flagging lesions with high malignancy risk and guiding referral urgency.

This study evaluates Legit.Health, an AI-driven platform that assigns urgency scores based on preliminary lesion analysis, ensuring high-risk patients see a dermatologist sooner while low-risk cases remain in primary care. We will assess its impact on referral prioritisation and wait-time reduction for suspected melanoma.
By enabling earlier detection of serious skin pathologies, Legit.Health aims to improve patient outcomes, optimise specialist resources, and reduce unnecessary consultations.

Study status
Planned

Research institutions and networks

Institutions

Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau – IIB Sant Pau

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Institution

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

Spain

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Institution | Non-Pharmaceutical company | Other

Contact details

Study institution contact

Alfons Medela alfonso@legit.health

Study contact

alfonso@legit.health

Primary lead investigator

Oriol Yélamos 0000-0002-8058-3095

Primary lead investigator

ORCID number:

0000-0002-8058-3095

Study timelines

Date when funding contract was signed
Actual: 28/06/2024

Study start date
Planned: 07/07/2025

Data analysis start date
Planned: 01/10/2026

Date of final study report
Planned: 01/11/2026

Sources of funding

- Other

More details on funding

This study was conducted thanks to the Seal of Excellence under Horizon 2020 the EU's Framework Programme for Research and Innovation.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Medical device

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Healthcare resource utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

A quasi-experimental study without a control group will be conducted to evaluate the impact of the Legit.Health device for the rescheduling of patient

follow-up visits. Patients will take photographs of their own skin lesions, which will be analysed by Legit.Health.

Main study objective:
The primary objective of this study is to evaluate the impact of the Legit.Health medical device on the prioritisation of dermatology follow-up visits in patients at risk of melanoma.

Secondary objectives include:
To evaluate the accuracy of the LH algorithm in estimating the diagnostic probability of various clinical dermatological conditions.
To estimate the mean wait time until the next visit after using the LH in patients at risk of melanoma and evaluate its potential benefit in reducing this risk.
To compare the number of in-person follow-up visits in the 6 months prior to using Legit.Health with the number of visits during the study (with the use of Legit.Health).
To evaluate healthcare professionals' satisfaction with the use of the Legit.Health medical device.
To evaluate patient satisfaction with the use of the Legit.Health medical device, and with the new care pathway.

Study Design

Non-interventional study design
Case-only
Cohort

Study drug and medical condition

Medicinal product name, other

The medical device under investigation is Legit.Health Plus

Medical condition to be studied

Malignant melanoma

Population studied

Short description of the study population

Adult patients (≥ 18 years) at risk of melanoma and treated in the dermatology department of the Hospital de la Santa Creu i Sant Pau in Barcelona will be recruited during a follow-up visit they had already scheduled with the Department, after confirming that they meet the inclusion criteria.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest, other

patients with dermatological lesions suspected of being malignant

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Estimated number of subjects

139

Study design details

Setting

This study will be carried out in the department of Dermatology of the Santa Creu i Sant Pau University Hospital. For this purpose, 140 patients suspected of malignancy will be recruited.

The study will have a duration of 16 months to be completed. Patients should meet the following acceptance criteria:

Patients at high risk for melanoma: patients with a personal or family history of melanoma, dysplastic nevus syndrome (>100 nevi with variability in shape, size, and/or color), patients with a known genetic mutation that increases the risk of familial melanoma (CDKN2A, CDK4, MITF, BAP1, POT1, TERT, MC1R polymorphisms, among others).

Patients aged 18 years or older.

Patients who have signed the informed consent form for the study.

Must have a smartphone.

Must know how to use WhatsApp (minimum digital proficiency).

In this way, the dermatologist will receive and review the images taken by patients. They will also review the output of the device and, with this data, will decide if this patient must be prioritised and see earlier by the dermatologist.

Data analysis plan

To evaluate the potential impact of implementing Legit.Health on follow-up visits, the rescheduling rate (%) and the average wait time until the next follow-up visit will be estimated.

In addition, the average reduction in wait time until the follow-up visit will be estimated, compared to regular scheduling.

Furthermore, the number of in-person follow-up visits during the 6 months prior to the start of the study will be compared with the number of in-person follow-up visits during the study to determine whether these decrease, remain the same, or increase.

To evaluate the accuracy of the HL risk score, the Area Under the Curve (AUC) will be calculated by class, using the final diagnosis at the final visit as the gold standard.
The level of satisfaction with Legit.Health among professionals will be measured using the System Usability Scale (SUS), and that of patients will be measured using a specific satisfaction questionnaire.
The scale scores will be analysed through a descriptive analysis of the overall scores obtained globally and for each dimension. All analyses will be conducted using Python or R software. P values < 0.05 will be considered statistically significant, and 95% confidence intervals will be applied to the estimates.

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)

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

Unknown