Pilot study for the clinical validation of a medical device for the automatic triage in teledermatology (Legit.Health_clinical_VH_2025)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000649

Study ID

1000000649

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Over the past three years, Barcelona's Vall d'Hebron University Hospital (HUVH) has implemented an innovative teledermatology system that has managed tens of thousands of cases.

This platform enables primary care physicians to submit referrals complete with images and designated urgency levels.

However, delays in non-urgent referrals—combined with a dermatology waiting time averaging 118 days across Catalan hospitals as of October 2023—have led to late diagnoses of malignant and urgent conditions.

Legit.Health offers an AI-driven solution that extracts clinically relevant data from dermatological images.

This output supports clinicians' decision-making and can also automate workflows such as patient prioritisation based on malignancy risk or severity criteria.

This project aims to optimise care for patients with skin cancer and serious dermatoses by reducing waiting times, improving the accuracy of skin-cancer detection, and lowering rates of false positives and negatives.

To achieve this, we will conduct a detailed analysis of over 30,000 teleconsultations between primary care and dermatology, alongside other pertinent data, to evaluate the tool's performance. Image quality will be monitored and non-malignant but urgent conditions—such as toxicodermias and extensive inflammatory dermatoses—will be identified for priority attention.

The introduction of Legit.Health at Vall d'Hebron promises to transform dermatological services through its advanced AI capabilities.

Nonetheless, before full deployment, this study will validate the tool's clinical

utility using real-world data.

Study status

Ongoing

Research institutions and networks

Institutions

University Hospital Vall d’Hebron (HUVH)

Spain

First published: 01/02/2024

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

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: 01/03/2025

Actual: 07/03/2025

Study start date

Planned: 15/03/2025

Actual: 28/03/2025

Data analysis start date
Planned: 01/08/2025

Date of final study report
Planned: 01/09/2025

Sources of funding

- No external funding

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:

Effectiveness study (incl. comparative)

Healthcare resource utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Retrospective study to assess the utility of a dermatology teleconsultation prioritisation algorithm based on machine learning.
Study sample: teleconsultations with images submitted from primary care (adult and paediatric) to the Dermatology Department between 13 July 2020 and December 2023.

Main study objective:

The impact of implementing Legit.Health on reducing the average waiting time for skin cancer patients will be measured.
To do so, both the mean wait time and the number of cases experiencing delays will be calculated and compared with the projected wait times once the Legit.Health algorithm is in place.
This will provide a clear assessment of the algorithm’s effectiveness in the early diagnosis and management of melanoma and other malignant conditions. The KPIs to be measured are:

Reduction in mean waiting time for skin cancer patients.

Sensitivity and specificity of Legit.Health in malignancy detection.

Number of false negatives by primary care physicians identified by Legit.Health. False negatives are those referred as non-urgent but later confirmed malignant, or reclassified as high priority upon subsequent dermatologist review.

Number of false positives by primary care physicians identified by Legit.Health. False positives are those referred as urgent but later deemed benign or low priority by the dermatologist.

Trends in the quality of submitted images over time, ensuring the average image quality remains consistently adequate.

Identification of non-malignant conditions requiring priority attention (e.g., drug eruptions and extensive inflammatory dermatoses).

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

Additional medical condition(s)
Skin conditions in primary care

Population studied

Short description of the study population

In this study, images from patients with different skin conditions and referred from primary care to dermatology will be analysed.

In this way, these patients were seen in primary care due to different skin conditions, and the primary care physician decided to refer them to dermatology.

In this way, we will assess if the use of the algorithm considers that the referral was acceptable and correct or not.

Age groups

Paediatric Population (< 18 years)

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

30000

Study design details

Setting

The study will be carried out in the Vall d'Hebron University Hospital. In order to assess the main objective and KPIs, images from patients referred from primary care to dermatology will be selected and analysed by the medical device.
The study will be conducted for 6 months and will assess whether the derivations were necessary and acceptable. The comparator here will be the derivation criteria of the primary care physician, which will be compared with the derivation criteria of the algorithm. The images should be from patients diagnosed with dermatological diseases by primary care physicians and subsequently referred to a dermatologist.

Comparators

In this study, the referral criteria and level of priority assigned by the primary care physician for referring the patient to dermatology will be compared with the priority assigned by the medical device, with the dermatologist assessing which of the two is correct or more accurate.

Data analysis plan

To validate the device, a comparative analysis will be conducted between the observed wait times and the possible wait times after prioritisation/triage through Legit.Health.
In addition, a concordance analysis will be performed between the artificial intelligence tool, dermatologists, and primary care physicians.
To this end, appropriate statistical tests will be used depending on the nature of the variables, as well as comparisons or estimates as appropriate.

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