Non-Invasive Prospective Pilot in a Live Environment for the improvement of the diagnosis of skin pathologies in primary care

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000644

Study ID

1000000644

DARWIN EU® study

No

Study countries

Spain

Study description

Dermatological conditions represent a significant portion of primary care consultations, constituting approximately 5% of all visits. However, discrepancies between diagnoses made by general practitioners and dermatologists remain substantial, with concordance rates between 57% and 65.52%.

This gap in expertise often leads to misdiagnoses, incorrect referrals, and delays in appropriate treatment, particularly in rare and severe conditions. The limited availability of dermatologists, especially in rural areas, further complicates patient care, underscoring the need for innovative solutions to optimize resource allocation and improve diagnostic accuracy.

Teledermatology has shown promise in reducing the pressure on in-person consultations by enabling remote assessments.

However, the adoption of artificial intelligence (AI) presents a transformative opportunity to enhance the diagnostic capabilities of general practitioners. The device has already been validated in the diagnosis of skin conditions and offers advanced tools, such as the automatic scoring of diverse pathologies. This pilot study aims to evaluate whether the use of the device can increase the true accuracy of healthcare professionals (HCPs) in the diagnosis of multiple dermatological conditions.

The main aim of this study is to validate that the information provided by the device increases the true accuracy of general practitioners in the diagnosis of multiple dermatological conditions.

This is a prospective observational analytical and cross-sectional study. It is designed to assess if the use of the medical device by dermatologists and general practitioners can increase the accuracy in the diagnosis of multiple dermatological conditions, who will be presented with 30 images of patients with different skin conditions.

In this case, the data collection will include the diagnosis accuracy for different dermatological pathologies.

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

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Study timelines

Date when funding contract was signed
Planned: 30/05/2024

Actual: 30/05/2024

Study start date
Planned: 04/06/2024

Actual: 04/06/2024

Date of final study report
Planned: 04/09/2024

Actual: 13/09/2024

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 topic, other:

Improvement in diagnostic accuracy of skin conditions in primary care

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

The study employed a prospective observational, analytical and cross-sectional design to evaluate whether the use of Legit.
Health improved the accuracy of the diagnosis of different skin pathologies by HCPs. This investigation encompassed a diverse cohort of 9 primary care physicians.

Main study objective:

To validate that the information provided by the device increases the true accuracy of primary care physicians in the diagnosis of multiple dermatological conditions. The secondary objectives are:
To validate what percentage of cases should be referred, according to the HCP, with the information provided by the device.
To validate what percentage of cases could be handled remotely with the information provided by the device.
The device should achieve:

- An improvement of at least 10% in diagnostic accuracy among general practitioners.
- A positive view of the device regarding diagnosis support.
- A reduction of 15% of referrals to dermatology.
- An improvement in remote consultations of at least 40% of patients.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Melanocytic naevus

Malignant melanoma

Basal cell carcinoma

Urticaria

Pustular psoriasis

Actinic keratosis

Psoriasis

Hidradenitis

Additional medical condition(s)

Atypical melanocytic naevus

Population studied

Short description of the study population

In this study, the population will consist of primary care physicians. A minimum of 9 physicians will be selected to participate in this study and review the images. On the other hand, the photos used in this study are from patients diagnosed with the conditions mentioned.

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

9

Study design details

Setting

This is a prospective observational and cross-sectional study. The study does not involve an active or control group, as the physicians will be their control group, firstly without using Legit.
Health and after making their diagnosis, using Legit. Health to assess if they want to change their diagnosis or keep it.
The assessment criteria include the assessment of different images with pathologies such as GPP or HS and their diagnosis. The study employs a variety of methods, including data collection through websites or photograph analysis.
This study enrolled primary care physicians to review the images and make a diagnosis. At the end of the study, 9 HCPs were enrolled. These doctors should evaluate 30 images of different skin pathologies and diagnose them.
The inclusion criteria include:
- Board-certified primary care physicians and dermatologists, regardless of their professional experience.
- High-quality images of patients with different skin conditions.
Exclusion criteria:
- Low-quality images of patients which can not be properly analysed.

In this study, the doctors will be their comparators, first annotating their diagnosis without using the medical device, and then using the device. In this case, the doctors will be asked if they want to change their initial diagnosis or change it.
Finally, an analysis of diagnostic accuracy will be carried out to assess whether the use of the device allows primary care physicians to improve their diagnostic accuracy on dermatological conditions.

Comparators

In this study, the doctors will be their comparators, first annotating their diagnosis without using the medical device, and then using the device.
In this case, the doctors will be asked if they want to change their initial diagnosis or change it.
Finally, an analysis of diagnostic accuracy will be carried out to assess whether the use of the device allows primary care physicians to improve their diagnostic accuracy on dermatological conditions.

Outcomes

In this study, nine primary care doctors reviewed all the images.

We conducted a McNemar test in order to analyse whether the information provided by Legit.Health impacts on the healthcare professionals' diagnostics. Overall, primary care doctors demonstrated an accuracy of 72.96%, which notably increased to 82.22% with the integration of Legit.Health.
Assessing the impact of Legit.Health on referrals, our findings revealed that 48.89% of cases did not necessitate a referral.
Furthermore, we examined the feasibility of handling cases remotely through teledermatology. The results show that 60.74% of the cases can be handled remotely.

Conducting a Pearson's chi-squared test on the necessity for referrals and teleconsultations, we concluded with 95% confidence that a strong association exists between referrals and remote consultations. Specifically:

36.67% of the cases do not require a referral and can have follow-up remotely
12.22% of the cases do not require a referral but require an in-person appointment
24.07% of the cases require a referral and remote consultation

27.04% of the cases require a referral in addition to an in-person appointment

Data analysis plan

To estimate the correlation between diagnoses with and without using Legit.Health, we analysed the concordance between diagnoses for both primary care physicians and dermatologists. We analysed whether Legit.Health reinforced the diagnosis of the physicians (after observing the results of Legit.Health, the doctor maintains the diagnosis when his answer matches that of the solution) if Legit.Health improves the practitioner's diagnosis (the doctor changes the diagnosis when his answer does not match that of the solution), if it has no impact (The doctor does not change the diagnosis even though his answer does not match that of the solution) and if it has a negative impact (The doctor changes the diagnosis for an answer that does not match that of the solution). We also analysed whether physicians considered that this case should be referred to a specialist or could be handled remotely.

Summary results

For this study, nine primary care doctors reviewed all the images, which were 30.

When HCPs did not use Legit.Health, they showed an accuracy of 72.96% on their diagnosis. On the other hand, when they integrated Legit.Health on their diagnosis, the accuracy increased to 82.22%. This increase was observed for all targeted conditions, excluding basal cell carcinoma.

In relation to the referrals, 48.89% of cases did not need a referral. Finally, regarding remote consultations, 60.74% of cases can be handled remotely.

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 source(s), other

Please note that the database used in this study is not publicly accessible due to privacy and confidentiality considerations.

Data sources (types)

Other

Data sources (types), other

Dermatological atlases, images from the company’s previous studies.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No