Optimization of Clinical Workflow in Patients with Various Dermatological Conditions through Artificial Intelligence (Legit.Health_IDEI_2023)

First published: 05/03/2024

Last updated: 08/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000045

Study ID

1000000045

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Artificial intelligence (AI) based on imaging holds tremendous potential to enhance visual diagnostic accuracy in the medical field. Amid the COVID-19 pandemic, limited access to in-person healthcare services drove shifts in medical care, hastening the adoption of telemedicine. In this context, AI usage for triage and decision support may be crucial for professionals to manage workload and improve performance. In dermatology, pigmented lesions, acne, and alopecia are three recurring pathology groups with high demand in dermatological centers. Both triage, clinical evaluation, and patient follow-up require in-person resources and specialist dedication. Employing tools like AI can benefit these professionals in reducing such processes and optimizing workload. Advancements in image recognition and interpretation, as well as in artificial intelligence, have spurred innovations in diagnosing various pathologies, including skin conditions. Computer-Aided Diagnosis (CAD) systems and other algorithm-based technologies have demonstrated the ability to classify lesion images with a competency comparable to that of an expert physician. In this study, the Legit.Health tool, developed by AI LABS GROUP S.L., which utilizes artificial intelligence to optimize clinical flow and patient care processes for skin conditions, will be evaluated. The purpose of this tool is to automatically prioritize patients with greater urgency, assign the type of consultation (dermatological or aesthetic), enhance diagnostic capability and detection of malignant pigmented lesions in auxiliary staff, and provide a visual record (photograph) of the condition for later review by external experts. Thus, the main objective of this study is to validate that Legit.Health, based on Artificial Intelligence, improves efficiency in clinical flow and patient care processes, thereby reducing time and cost of patient care through enhanced diagnostic accuracy and severity determination.

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

IDEI Hospital

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Miguel Sánchez-Viera

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 25/01/2024

Actual: 25/01/2024

Study start date
Planned: 01/03/2024

Actual: 01/03/2024

Data analysis start date
Planned: 30/04/2024

Date of final study report
Planned: 31/05/2024

Sources of funding

- National competent authority (NCAs)

More details on funding

Call for grants 2021 aimed at Research and Development projects in Artifical Intelligence and other digital technologies and their integration into value chains. Ministry for Digital Transformation and Public Function.

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:

Disease /health condition

Medical device

Study topic, other:

Diagnosis of different skin pathologies

Study type:

Non-interventional study

Scope of the study:

Method development or testing

Validation of study variables (exposure outcome covariate)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Study Design Type: This is an observational study, both prospective with a longitudinal character and retrospective case series.

Study Period: This study estimates a recruitment period of 3 months.
The total study duration is estimated at 6 months, including the time for retrospective analysis

Main study objective:
The main objective of this study is to validate that Legit.Health, based on Artificial Intelligence, improves efficiency in clinical flow and patient care processes, thereby reducing time and cost of patient care through enhanced diagnostic accuracy and severity determination.

Study Design

Non-interventional study design
Cohort
Cross-sectional

Study drug and medical condition

Medical condition to be studied
Acne
Androgenetic alopecia
Skin lesion

Additional medical condition(s)
Pigmented lesions suspected of malignancy

Population studied

Short description of the study population

- Patients with pigmented lesions and suspected malignancy
- Patients with pigments skin lesions, which are suspected malignancy. The practitioners will take a photo of the lesion and upload into the tool so as to confirm both the diagnosis and suspicion of malignancy
- Patients diagnosed with acne
- Patients treated at IDEI hospitals and diagnosed with acne. Practitioners will take a photo of patients' face and upload it into the tool so as to check the severity of acne and compare it with the gold standard
- Patients diagnosed with femenine androgenetic alopecia
- Patients treated at IDEI hospitals and diagnosed with femenine androgenetic alopecia. Practitioners will take a photo of the top of the head and upload it into the tool so as to check the severity of alopecia and compare it with the gold standard

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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)

Estimated number of subjects

150

Study design details

Setting

This is an observational study, both prospective with a longitudinal character and retrospective case series.

Study Period: This study estimates a recruitment period of 3 months. The total study duration is estimated at 6 months, including the previous time for retrospective analysis and the necessary time after recruiting the last subject for database closure and editing, data analysis, and preparation of the final study report. The total study duration for each participant with pigmented lesions will be 1-3 months. The duration for patients with acne and alopecia will be 1 day.

Study Population: Adult patients (≥ 18 years) with skin pathologies treated at the Dermatology Unit of IDEI.

Outcomes

Primary Outcome Measure: Concordance between the physician's diagnosis and that of the tool.

Analysis of concordance between the diagnosis issued by the dermatologist and that determined by the Legit.Health tool.

Time Frame: At the moment of enrollment up to 1 year.

Primary Outcome Measure: Agreement of detected malignancy between the dermatologist and Legit.Health tool.

Correlation analysis of the suspected malignancy between the dermatologist and the Artificial Intelligence tool.

Time Frame: At the moment of enrollment up to 1 year.

Secondary Outcome Measure: Acne severity.

Severity of acne assessed by both physicians and Legit.Health tool through lesion counting. A correlation analysis will be performed to check differences of criteria between them.

Time Frame: At the moment of enrollment up to 1 year.

Secondary Outcome Measure: Severity of alopecia.
Severity of androgenetic alopecia assessed by both physicians and Legit.Health tool with the Ludwig scale. A correlation analysis will be performed to check differences of criteria between them.
Time Frame: At the moment of enrollment up to 1 year.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Population registry

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

Yes

Data characterisation

Data characterisation conducted

Unknown