Clinical Validation of a Computer-Aided Diagnosis (CAD) System Utilizing Artificial Intelligence Algorithms for Continuous and Remote Monitoring of Patient Condition Severity in an Objective and Stable Manner. (LEGIT_COVIDX_EVCDAO_2022.)

First published: 03/01/2024

Last updated: 01/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS108260

Study ID

108261

DARWIN EU® study

No

Study countries

Spain

Study description

This clinical investigation examines the Legit.Health software medical device, utilizing advanced machine vision and deep learning for dermatological diagnostics.

With 160 patients, the study prioritizes ethical standards and regulatory compliance, potentially transforming dermatological diagnostics.

The primary objective is to validate the device's effectiveness in tracking chronic dermatological conditions, aiming for a Clinical Utility Questionnaire score of 8 or higher.

Secondary objectives include confirming high patient satisfaction with remote device application, assessing the device's impact on reducing face-to-face consultations, and validating its reliability in consistently monitoring conditions.

The study encompasses patients with chronic dermatological conditions meeting inclusion criteria at the Dermatology Department of Hospital Universitario de Torrejón.

The design involves a six-month recruitment period, informed consent, and initial supervised device use. Patients autonomously complete questionnaires, use the Dermatology Life Quality Index, and submit pathology photographs through Legit.Health.

With 160 patients recruited, the study initiated on March 03, 2022, and completed on October 23, 2023, spanning a total duration of 19 months.

The results indicate positive outcomes, with specialists perceiving ease of use and effectiveness in optimizing consultation time.

The Data Utility questionnaire affirms the device's usefulness, and high user satisfaction and ease of navigation are reflected in System Usability Scale results. Positive patient satisfaction scores were observed, and no adverse events were noted, indicating a favorable safety profile.

In conclusion, the Legit.Health device proves highly effective, safe, and user-

friendly for managing chronic dermatologic conditions. Positive feedback from specialists and patients highlights its potential as a valuable clinical tool, offering objective follow-up in skin evaluation.

Study status

Finalised

Research institutions and networks

Institutions

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

Spain

First published: 08/03/2024

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Institution | Non-Pharmaceutical company | Other

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2022

Actual: 01/03/2022

Study start date
Planned: 03/03/2022

Actual: 03/03/2022

Date of final study report
Planned: 23/10/2023

Actual: 23/10/2023

Sources of funding

- EU institutional research programme
- Other

More details on funding

COVID X Initiative, as can be seen in the following page: https://www.covid-x.eu/game-changers/

Study protocol

LEGIT_COVIDX_EVCDAO_2022 Protocol Multipathology_v_2_0_EN.docx-5e3dc4ebfabd52f146d349d035e59f5c (1).pdf (3.81 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

https://www.biocrucesbizkaia.org/servicios/medtech Website where our study is registered as a beneficiary of the MEDTECH funding programme.

NCT06237036

https://register.clinicaltrials.gov/prs/beta/studies/S000E3L800000026/recordSum...

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

This study aims to: Evaluate the effectiveness of the device in remotely monitoring the severity of chronic dermatologic pathologies. Assess patient satisfaction with the device for remote monitoring.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Patients diagnosed with any of the specified chronic dermatological conditions that meet the inclusion criteria.

These patients are attended at the Dermatology Department of the Hospital Universitario de Torrejón.

It encompassed a diverse patient cohort with a range of chronic dermatologic pathologies, providing a comprehensive representation of the population affected by these conditions.

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

Study design details

Outcomes

Primary Analyses - Clinical Utility Questionnaire Specialists found the device easy to use, optimized consultation time, and enhanced data collection. General satisfaction was high, with an overall mean score of 71.39.
Statistical Analysis A one-sample Student's t-test suggested no substantial evidence to reject the hypothesis, aligning the observed sample mean with a population mean of 80, Data Utility Questionnaire: Specialists unanimously agreed on app usefulness. Mean scores revealed strong preferences for app functionalities, with some variations.
System Usability Scale Questionnaire: Specialists found the device easy to use, with positive feedback on integration. Discrepancies encountered indicated areas for improvement.

Data analysis plan

For the purpose of estimating mean responses and their variability, we calculated the mean and standard deviation for all questions.
Additionally, to evaluate the hypothesis concerning the CUS value, we conducted a one-sample Student's t-test to determine the statistical significance and either accept or reject the hypothesis based on the test results.

Documents

Study, other information

CEIm_LEGIT_COVIDX_EVCDAO_2022_TRJON-8abc0f12d828135f5b5e7bf93985ee24.pdf (317.94 KB)

Study publications

Clinical Validation of a Computer-Aided Diagnosis (CAD) System Utilizing Artifi...

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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