Description of the cutaneous manifestations of Covid-19 (COVID-PIEL)

First published: 02/04/2020
Last updated: 01/07/2024

Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/34470

EU PAS number
EUPAS34469

Study ID
34470

DARWIN EU® study
No

Study countries
Spain

Study description
Observational transversal descriptive study with the main objective to describe the clinical characteristics and symptoms of the cutaneous manifestations associated with COVID-19.The secondary objectives are:o Identify the chronology of the cutaneous manifestations associated with COVID-19.o Evaluate the eventual relationship of skin manifestations with current COVID-19 treatments.o Evaluate the relationship of cutaneous manifestations associated with analytical parameters.

Study status
Planned

Research institution and networks

Institutions

Hospital Universitario de Móstoles

First published: 01/02/2024
Last updated 01/02/2024

Institution

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain
First published: 01/02/2024
Last updated 01/07/2024

Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority

Hospital Plato Barcelona, Hospital Universitario de Gran Canaria Doctor Negrín Las Palmas de Gran Canaria

Contact details

Study institution contact
Cristina Galvan Casas
Study contact

covidpiel@gmail.com
Primary lead investigator
Cristina Galvan Casas
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
31/03/2020

Study start date
Planned:
06/04/2020

Data analysis start date
Planned:
21/04/2020

Date of interim report, if expected
Planned:
21/04/2020

Date of final study report
Planned:
30/04/2020

Sources of funding

- Other

More details on funding

Principal Investigators

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

ACG-CLO2020-01Agencia Española del Medicamento

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology

Main study objective:
To describe the clinical characteristics and symptoms of the cutaneous manifestations associated with COVID-19.

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

Medical condition to be studied
Rash erythematous

Population studied

Age groups
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)
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)

Special population of interest
Hepatic impaired
Immunocompromised
Pregnant women
Renal impaired

Estimated number of subjects
60

Study design details

Outcomes
o Identify the chronology of the cutaneous manifestations associated with COVID-19.o Evaluate the eventual relationship of skin manifestations with current COVID-19 treatments.o Evaluate the relationship of cutaneous manifestations associated with analytical parameters

Data analysis plan
The statistical analysis includes descriptive statistics using absolute frequencies and percentages. The chi-square test and odds ratio calculation will be used to test the association between skin manifestations, COVID-19 treatments and analytical parameters indicating severity.

Data management

Data sources

Data sources (types)
Spontaneous reporting system

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