

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

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Study

Planned

## Administrative details

### 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.

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## Study status

Planned

## Research institutions and networks

### Institutions

[Hospital Universitario de Móstoles](#)

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**Institution**

[Hospital Plato Barcelona, Hospital Universitario de  
Gran Canaria Doctor Negrín Las Palmas de Gran  
Canaria](#)

## Contact details

### Study institution contact

Cristina Galvan Casas covidpiel@gmail.com

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

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**Study start date**

Planned: 06/04/2020

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**Data analysis start date**

Planned: 21/04/2020

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**Date of interim report, if expected**

Planned: 21/04/2020

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**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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

ACG-CLO2020-01 Agencia Española del Medicamento

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**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)

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### **Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

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### **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
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### **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 reports of suspected adverse drug reactions

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No