

# The PsoProtect Research Database (Psoriasis Patient Registry for Outcomes, Therapy and Epidemiology of Covid-19 infection)

**First published:** 18/06/2020

**Last updated:** 14/03/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS35860

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### Study ID

35861

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### DARWIN EU® study


No







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### Study countries

 Argentina

 Australia

 Austria

-  Belgium
  -  Brazil
  -  Canada
  -  Chile
  -  Colombia
  -  France
  -  Germany
  -  India
  -  Iran, Islamic Republic of
  -  Italy
  -  Luxembourg
  -  Malaysia
  -  Mauritius
  -  Netherlands
  -  Norway
  -  Peru
  -  Philippines
  -  Poland
  -  Spain
  -  Sweden
  -  Thailand
  -  Türkiye
  -  United Arab Emirates
  -  United Kingdom
  -  United States
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## **Study description**

PsoProtect (Psoriasis Patient Registry for Outcomes, Therapy and Epidemiology of Covid-19 infecTion) is an international registry for reporting outcomes of COVID-19 in individuals with psoriasis and related IMIDs (rheumatic diseases

and atopic dermatitis). By collecting observational data on cases of COVID-19 in psoriasis and related IMIDs on a global scale, PsoProtect has the potential to rapidly improve our understanding of how factors such as systemic immunomodulator/immunosuppressant therapies, comorbidities and demographic variables including age, sex and ethnicity affect outcomes of COVID-19 in IMIDs, for the benefit of the international clinical community. PsoProtect is closely aligned with recently established partner databases for clinician-reported outcomes to COVID-19 in other IMIDs (such as [www.coviibd.org](http://www.coviibd.org) and [www.rheum-covid.org](http://www.rheum-covid.org)). We will continue to collaborate closely with these research teams in order to facilitate valuable cross-disease analyses. The primary objective is to uncover the underlying determinants of the outcome of COVID-19 in psoriasis and the related IMIDs rheumatic diseases and atopic dermatitis. Specifically, we will determine the impact of immunomodulator/immunosuppressant therapies, comorbidities and demographic variables such as age, sex and ethnicity on outcomes of COVID-19 in IMIDs. The secondary objectives are to determine the impact of COVID-19 on the disease course/severity of psoriasis and related IMIDs (rheumatic diseases and atopic dermatitis), and to determine the impact and outcomes of COVID-19 across diseases and therapies, and create a data resource to enrich other allied datasets through cross-disease collaboration. This is an observational cohort study of outcomes to COVID-19 in psoriasis and related IMIDs. Real-world observational clinical data is collected using the web-based clinician and patient facing PsoProtect case report forms (designed using the REDCap platform).

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## **Study status**

Planned

## **Research institutions and networks**

### **Institutions**

# St John's Institute of Dermatology

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Satveer Mahil

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 27/03/2020

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### Study start date

Planned: 27/03/2020

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### Date of final study report

Planned: 31/03/2025

## Sources of funding

- Other

## More details on funding

NIHR Biomedical Research Centre at Guy's and St Thomas' NHS Foundation Trust and King's College London, The Psoriasis Association (UK)

## 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

IRAS Reference: 282395 REC reference:

20/YH/0135 <https://psoprotect.org/> <https://psoprotectme.org/>

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To uncover the underlying determinants of the outcome of COVID-19 in psoriasis and the related IMIDs rheumatic diseases and atopic dermatitis.

Specifically, we will determine the impact of

immunomodulator/immunosuppressant therapies, comorbidities and

demographic variables such as age, sex and ethnicity on outcomes of COVID-19 in IMIDs.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Psoriasis

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**Additional medical condition(s)**

Clinicians enter the details of their cases of COVID-19 in psoriasis using the online PsoProtect case report form. Patients with psoriasis, rheumatic disease or atopic dermatitis are able to self-report using the patient-facing case report

forms.

## 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**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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### **Estimated number of subjects**

5000

## Study design details

### **Outcomes**

### **Data analysis plan**

1) Univariable analysis (unadjusted) to compare demographic /disease characteristics according to hospitalisation status Summarise N (%) or Median (IQR) for categorical/continuous respectively. For each variable (e.g. age, ethnicity, sex, treatment, comorbidities), compare hospitalised vs non-hospitalised groups and report p-value, using:

- o Chi-square test for each categorical variable
- o Mann Whitney U test for each continuous variable

2) Multivariable-adjusted logistic regression to assess the associations between demographic/disease specific features and hospitalisation from COVID-19 -

Table 2 • Report:

- o Unadjusted/univariable model: odds ratios (95% CI)
- o Adjusted/joint model: odds ratios (95% CI) and P-value

## 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 sources (types)**

[Disease registry](#)

Other

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**Data sources (types), other**

Prospective patient-based data collection

## 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