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

Study ID

35861

DARWIN EU® study

No

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

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 and 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).

Study status

Planned

Research institutions and networks

Institutions

St John's Institute of Dermatology

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Institution

Contact details

Study institution contact

Satveer Mahil PsoProtect@kcl.ac.uk

Study contact

PsoProtect@kcl.ac.uk

Primary lead investigator

Satveer Mahil

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/03/2020

Study start date

Planned: 27/03/2020

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

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

Not applicable

Other study registration identification numbers and links

IRAS Reference: 282395REC reference: 20/YH/0135https://psoprotect.org/https://psoprotectme.org/

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

5000

Study design details

Outcomes

Hospitalization due to COVID-19, Death due to COVID-19Change in psoriasis/IMID severity during COVID-19

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 variableo Mann Whitney U test for each continuous variable2) 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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No