Effects of baricitinib on respiratory function in patients treated with corticosteroids for SARS-CoV-2 pneumonia: an observational cohort study (BARI-COVID19)

First published: 14/08/2020

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Study Finalised

Administrative details

EU PAS number

EUPAS34966

Study ID

34967

DARWIN EU® study

No

Study countries

Spain

Study description

Objectives. The Janus kinase (JAK) inhibitor baricitinib may block viral entry into pneumocytes and prevent cytokine storm in patients with SARS-CoV-2 pneumonia. We aimed to assess whether baricitinib improved pulmonary function in patients treated with high-dose corticosteroids for moderate to severe SARS-CoV-2 pneumonia.Methods. This observational study will enroll patients with moderate to severe SARS-CoV-2 pneumonia (PaO2/FiO2 less than 200 mmHg) who received either lopinavir/ritonavir and hydroxychloroquine plus corticosteroids (CS group, n=50) or plus corticosteroids and baricitinib (BCT-CS group, n=62). The primary endpoint is the change in SpO2/FiO2 (oxygen saturation as measured by pulse oximetry, SpO2/fraction of inspired oxygen, FiO2) from hospitalization to discharge. Secondary endpoints include the proportion of patients requiring supplemental oxygen at discharge and one month later. Statistics will be adjusted by the inverse propensity score weighting (IPSW).

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jose Luis Rodríguez García

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/05/2020

Actual: 28/04/2020

Study start date
Planned: 01/04/2020

Actual: 28/04/2020

Data analysis start date
Planned: 15/05/2020

Actual: 28/04/2020

Date of interim report, if expected
Planned: 22/05/2020

Actual: 28/04/2020

Date of final study report
Planned: 31/05/2020

Actual: 28/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Lilly

Study protocol

Protocolo_baricitinib_registro_europeo.pdf (156.95 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To determine whether the JAK inhibitor baricitinib could offer a beneficial or additive effect to corticosteroids on respiratory function in patients with moderate to severe ARDS due to SARS-CoV-2 pneumonia.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Baricitinib

Medical condition to be studied

COVID-19 pneumonia

Population studied

Short description of the study population

Patients older than 18 years admitted to the hospital because of SARS-CoV-2 pneumonia who have an arterial oxygen partial pressure/fractional inspired oxygen (PaO2/FiO2) ratio less than 200 mmHg on ward (moderate to severe

SARS-CoV-2 pneumonia).
All patients admitted during observation period with SARS-CoV-2 pneumonia and respiratory insufficiency (SpO2 ≤ 92% breathing room air) are considered for the
study. Patients older than 80 years or discarded for ICU will be transferred to a geriatric hospital admission whenever there are beds available. Patients are excluded if they have major comorbidities (chronic heart failure, chronic obstructive pulmonary disease on oxygen therapy, obstructive sleep apnea syndrome with continuous positive airway pressure, advanced chronic kidney disease, active malignancies). Patients will be also excluded if they have previously been treated with other immunomodulators (IVIG, INF, anakinra, tocilizumab). Patients admitted to ICU or who died will be considered nonevaluable and thus excluded.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

COVID-19 pneumonia patients

Estimated number of subjects

100

Study design details

Outcomes

The primary endpoint is defined as the change in SpO2/FiO2 from hospitalization to discharge. Secondary endpoints include the proportion of patients requiring supplemental oxygen at discharge and one month later.

Data analysis plan

We will adjust the analysis of outcome variables using the inverse propensity score weighting (IPSW), which is based on propensity score, to construct a weighted cohort of patients who differed with respect to treatment received but were similar regarding other measured characteristics. To calculate the IPSW will be use a logistic-regression model.

Documents

Study results

Protocolo_baricitinib_registro_europeo_resultados_resumen.pdf (103.27 KB)

Study publications

Yang Z, Liu J, Zhou Y, Zhao X, Zhao Q, Liu J. The effect of corticosteroid trea…

Fadel R, Morrison AR, Vahia A, Smith ZR, Chaudhry Z, Bhargava P, Miller J, Kenn…

Horby P, Lim WS, Emberson J, Mafham M, Bell J, Linsell L, Staplin N, Brightling…

Seif F, Aazami H, Khoshmirsafa M, Kamali M, Mohsenzadegan M, Pornour M, Mansour…

Stebbing J, Krishnan V, de Bono S, Ottaviani S, Casalini G, Richardson PJ, Mont…

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.

Conflicts of interest of investigators

Author Disclosure Statement.pdf (98.27 KB)

Data sources

Data sources (types)

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