EFFECTIVENESS AND SAFETY OF TOCILIZUMAB IN INTERSTITIAL PNEUMONIA WITH SERIOUS RESPIRATORY FAILURE SECONDARY TO SARS-COV-2 INFECTION (COVID-19): COHORT STUDY (TOCICOV-19)

First published: 31/03/2020

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS34415

Study ID

45837

DARWIN EU® study

No

Study countries

Spain

Study description

This is a prospective multi-center cohort post-authorization drug study. A percentage of the patients included in this cohort will be recruited retrospectively, therefore, the overall study design is ambispective. From the patients admitted to the hospital for COVID-19 with a diagnosis of interstitial pneumonia with severe respiratory failure, two cohorts will be selected based on their exposure (or not) to treatment with tocilizumab. The study will be carried out under real healthcare conditions. Data will be collected from days 1, 3, 7, 15 and 28 post inclusion (or treatment)

Study status

Finalised

Research institutions and networks

Institutions

Clinical Pharmacology Service, Puerta de Hierro-Majadahonda University Hospital (HUPHM)

Spain

First published: 26/12/2012

Last updated: 20/08/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility**

Clinical Pharmacology Service, Puerta de Hierro-Majadahonda University Hospital (HUPHM)

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HOSPITAL UNIVERSITARIO DE PUERTO REAL Spain, HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO Spain, HOSPITAL UNIVERSITARIO TORRECÁRDENAS Spain, HOSPITAL UNIV. GERMANS TRIAS I PUJOL Spain, HOSPITAL DEL MAR- PARC DE SALUT MAR Spain, HOSPITAL DE LA SANTA CREU I SANT PAU Spain, HOSPITAL UNIVERSITARIO DE CANARIAS Spain, HOSPITAL UNIVERSITARIO Nra Sra. CANDELARIA/ C.H. UNIV. DE SANTIAGO DE COMPOSTELA Spain, HOSPITAL UNIVERSITARI DE BELLVITGE/ HOSPITAL UNIVERSITARIO GREGORIO MARAÑON/HOSPITAL UNIVERSITARIO CLÍNICO SAN CARLOS/ HOSPITAL UNIVERSITARIO RAMÓN Y CAJAL Spain, HOSPITAL

GENERAL UNIVERSITARIO DE VALENCIA/ HOSPITAL INFANTA CRISTINA BADAJOZ/ HOSPITAL DE CÁCERES/ HOSPITAL UNIVERSITARIO DE LA PRINCESA/ HOSPITAL CENTRAL DE LA DEFENSA GÓMEZ ULLA Spain

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Belen Ruiz-Antoran

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/04/2020

Actual: 06/04/2020

Study start date

Planned: 09/04/2020

Actual: 10/04/2020

Data analysis start date
Planned: 23/04/2020

Date of interim report, if expected
Planned: 01/05/2020

Date of final study report
Planned: 15/05/2020

Actual: 07/09/2020

Sources of funding

- Other

More details on funding

Own funds

Study protocol

PROTOCOLO ESTUDIO DE COHORTES TOCI VERSION 0_REV.pdf (866.64 KB)

PROTOCOLO ESTUDIO DE COHORTES TOCI VERSION 1.0 08042020.pdf (403.65 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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To assess the effectiveness and safety of tocilizumab in the treatment of interstitial pneumonia due to COVID19 with severe respiratory failure treated at the hospitalization ward to prevent the need for mechanical ventilation and ICU admission.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TOCILIZUMAB

Medical condition to be studied

Coronavirus test positive

Pneumonia

COVID-19

Population studied

Short description of the study population

The study population were adult patients (≥ 18 years) with COVID-19, confirmed by PCR on nasopharyngeal swab, who were consecutively admitted to the participating hospitals between 3 March and 20 April 2020.

Age groups

- 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

Other

Special population of interest, other

COVID-19 patients

Estimated number of subjects

393

Study design details

Outcomes

% of patients with an event on day 15. Event is defined as: admission to the ICU by COVID-19 or death after admission by COVID-19. % of patients with an event on the day on days 1, 3, 7 and 29. Time to event Mortality on day 15 and 29 % of patients in need of oxygen therapy in each of its modalities Hospitalization time Change in the analytical levels % of patients with SAEs

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Data analysis plan

490/5000 The incidence in exposed (cohort treated with tocilizumab) and in non-exposed (untreated cohort) will be calculated for each of the effectiveness variables. From these, the measures of association relative risk (RR), absolute risk reduction (RAR) and relative risk reduction (RRR) will be calculated for each

of the variables, with their 95% CIs. Additionally, the odds ratios (OR) will be calculated. The RR adjusted for comorbidities and prognostic factors will be estimated.

Documents

Study results

40121_2020_Article_373.pdf (886.97 KB)

Study publications

Fernández-Cruz A, Ruiz-Antorán B, Muñoz-Gómez A, Sancho-López A, Mills-Sánchez ...

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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