ISRCTN44151777 https://doi.org/10.1186/ISRCTN44151777

Methylprednisolone versus dexamethasone in patients with COVID-19

Submission date
21/01/2022

Recruitment status
No longer recruiting

Registration date
24/01/2022

Overall study status
Completed

Last Edited
24/10/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Since the beginning of the COVID-19 pandemic, corticosteroids have been used to control the inflammatory response. Inflammation is normal in response to injury or infection, but it can be dangerous if it is not controlled.
The present study aims to evaluate the efficacy of early intravenous administration of methylprednisolone in all-cause mortality rates at 28 days after randomization in adult patients with COVID-19.

Who can participate?
Adults over the age of 18, diagnosed with COVID 19 and that needed hospitalization.

What does the study involve?
The intervention group received methylprednisolone associated with the standard treatment for COVID-19, while the control group received dexamethasone associated with the standard treatment for COVID-19.

What are the possible benefits and risks of participating?
The possible risks are the consequences of the disease itself, and the side effects of the corticosteroids that are being used in the study. As a consequence of COVID-19 it is possible to develop thromboembolic events, bleedings, need for ICU, need for respiratory support, death. Direct benefits to participants are not guaranteed. This is a study to verify the real effectiveness of a medication that is already formally recommended for the treatment of COVID-19.

Where is the study run from?
The MEDEX study is being run by the Núcleo de Pesquisa do Hospital do Rocio (Rocio Hospital Research Center) and takes place at the Hospital do Rocio (Rocio Hospital), in south Brazil.

When is the study starting and how long is it expected to run for?
July 2021 to September 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
47957821.2.0000.5529

Study information

Scientific Title
Evaluation of the effectiveness of methylprednisolone versus dexamethasone in patients with COVID-19

Acronym

MEDEX

Study objectives
The early administration of methylprednisolone increases the number of days alive and free from mechanical ventilation, and / or reduces the length of hospital stay, in adult patients with moderate or severe acute respiratory syndrome resulting from COVID-19.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2021, Brazilian National Research Ethics Committee (Brasília - Distrito Federal - Brazil, North Wing, SRTV 701, Via W 5 Norte, lote D - Edifício PO 700, 3º floor, CEP: 70719-040; + 55 61 3315-5878; conep@saude.gov.br), ref: 47957821.2.0000.5529

Study design
Prospective randomized controlled single-center open comparative clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The study presents two groups. The “Rocio Group” is the intervention group, while the “Recovery Group” is the control group.
The intervention group received daily intravenous methylprednisolone for 3 days, followed by a daily dose of 1 mg/kg/day for 7 days. The control group received a daily dose of 6 mg of dexamethasone intravenously for 10 days or until discharge, whichever comes first.
Both groups received standard care for critically ill and potential critical patients. The standard care included: follow-up diary by the Assistant Physician in the infirmary unit; Monitoring by the ICU Diarist Physician; monitoring, adjustment of conducts and care of intercurrences by the ICU on-duty Physician (for patients in ICU); continuous hemodynamic and ventilatory monitoring; monitoring of vital data following the ICU routine (for patients in ICU); motor and respiratory physiotherapy; ventilatory support measures, invasive or not; hemodynamic support measures, with or without vasopressors, as medically indicated (for patients in ICU); hydro-electrolyte and acid-base control; medical and general procedures, such as central venous access puncture,

closed chest drainage, tracheostomy, among others; use of antimicrobials (antibiotics, antivirals, antifungals, bacteriostatics, etc). according to medical advice; any treatment used adjunct that does not interfere with the evaluation; laboratory routine according to the unit routine and/or medical indication.
Follow-up included laboratory data on the third day, on the seventh day, on tenth day of randomization and on discharge day. All patients were followed until day 28 after randomization. The study is a single randomized paired into two equal groups. Randomization took place in the ward the day after hospital admission and was carried out by the research coordinator and informed to the assistant physician. The study is not blinded randomization, however, the statistical analysis of data is blinded.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Methylprednisolone, dexamethasone

Primary outcome measure
All-cause mortality rates at 28 days after randomization measured using patient records

Secondary outcome measures
Measured using patient records:
1. Length of hospital stay
2. Need or not for referral to the ICU
3. Length of ICU stay between randomization and day 28
4. Time of mechanical ventilation between randomization and day 28
5. Changes in laboratory standards after 72 hours, 7 days and 10 days of randomization

Overall study start date
27/07/2021

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Age ≥18 years.
2. Confirmed or suspected infection for COVID-19.
3. Need for hospitalization, infirmary or intensive care unit (ICU).
4. Chest tomography with image compatible with COVID-19.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Total final enrolment
400

Key exclusion criteria
1. Known history of allergy to metrilprednisolone.
2. Use of corticosteroids for another condition.
3. Patient's refusal to participate in the study.
4. Pregnant or breastfeeding women.
5. Contraindication to the use of corticosteroids.

Date of first enrolment
15/08/2021

Date of final enrolment
20/09/2021

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital do Rocio
Maria Aparecida de Oliveira Street nº 599
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Sponsor information

Organisation
Hospital do Rocio

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	06/07/2021	24/01/2022	No	No
Other unpublished results			24/10/2022	No	No