Republic of Colombia
Ministry of Health and Social Protection National
Institute for Food and Drug Surveillance - INVIMA

RESOLUTION No. 2020029493 of September 7, de 2020

By which a Protocol for Clinical Research with Medicines is approved in the framework of the Health Emergency generated by COVID-19

The Technical Director of Medicines and Biological Products of the Invima National Institute for the Surveillance of Medicines and Foods, delegated by resolution number 2012030820 of October 19, 2012, in exercise of the Legal powers Conferred in Decree 2078 of 2012, Regulatory Decree 677 of 1995, Resolution 2378 of 2008, Law 1437 of 2011 and Law 1755 of 2015.
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FILE: 20180044 **RADICATION:** 20201092763 **DATE:** 26/05/2020

BACKGROUND

That by means of letter No. 20201092763 of May 26, 2020, Doctor Ramiro del Carmen Posada Agudelo, acting as Manager of the Somer clinic, requested authorization to carry out the BIOXSOMCOV001 clinical study entitled "*Efficacy and safety of the venous application of Wharton's jelly-derived mesenchymal stem cells from the umbilical cord added to standard therapy for the treatment of patients diagnosed with acute respiratory distress syndrome by COVID 19, a randomized controlled clinical trial* "

That by means of order No. 2020006741 of June 12, 2020, the Directorate of Medicines and Biological Products, I request the interested party to provide information related to: Methodological design, informed consents, researcher's manual, certifications from competent authorities for the performance of particular activities of the research protocol.

That by means of filing No. 20201143435 of August 18, 2020, Doctor Ramiro del Carmen Posada Agudelo, acting as Manager of the Somer clinic, provided a response to the requirements made by this institute.

That by means of filing No. 20201147775 of August 24, 2020, Doctor Ramiro del Carmen Posada Agudelo, acting as Manager of the Somer clinic, allege that he reached an auto response.

That by means of filing No. 20201150763 of August 27, 2020, Dr. Alfredo Hernández Ruiz acting as Principal Investigator of the Research and Teaching Unit of the Somer Clinic, I reach a response to the order.

DISPATCH CONSIDERATIONS

That once the documentation provided by the interested party has been reviewed, this office is allowed to make the following considerations:

That this research protocol was previously approved by the *Somer Clinic Research Ethics Committee.*

That the research protocol associated with the institute has a design, methodology, collection and analysis of data suitable for obtaining the objective proposed in it.

That for the development of this clinical trial, BioXcellerator S.A.S, in charge of the collection of mesenchymal stem cells derived from Wharton's gelatin from the umbilical cord, complies with current regulations.

That the useful lifetime assigned for the product under investigation covered by this resolution was supported by technical documentation according to current legal regulations for this type of products.

That both the research center and the principal investigator meet the criteria established for the development of the clinical study in question.

That in accordance with the provisions of the guidelines for the presentation and evaluation of clinical studies with drugs or products for COVID-19, once the clinical study has been approved by Invima, the person responsible for the Rionegro Medical Society-Somer Clinic protocol, acquires the commitment to report monthly the status of its progress, which includes information regarding Serious Adverse Events (SAE) presented.

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Likewise, they must report to Invima all serious adverse events related to deaths, within a period of no more than twenty-four (24) hours from the date on which the sponsor / CRO is notified of their occurrence. The rest of the serious adverse events must be reported to Invima by the Rionegro Medical Society-Somer Clinic, within a period of no more than seven (7) business days counted from the date the sponsor is notified.

That according to the provisions of article 11 of Resolution 8430 of 1993, research on drugs is considered as research with a risk greater than the minimum, and that according to article 6 of Resolution 2378 of 2008, Invima may interrupt at any time to carry out a clinical investigation or demand the introduction of modifications in your project, in the following cases: a) Alteration of the authorization conditions. b) Non-compliance with Good Clinical Practices. c) Protection of human test subjects. d) Defense of public health.

That based on Article 6 of Resolution No. 3823 of 1997, Article 5 of Resolution No. 2378 of 2008, and with a prior technical-legal study of the documentation provided by the interested party.

Consequently, the Directorate of Medicines and Biological Products,

RESOLVES

ARTICLE ONE: APPROVE the development of the following clinical research protocol:

Protocol Title: Efficacy and safety of the venous application of mesenchymal stem cells derived from wharton's gelatin from the umbilical cord added to standard therapy for the treatment of patients diagnosed with acute respiratory distress syndrome by Covid 19, a randomized controlled clinical trial
Sponsor and / or CRO: Rionegro Medical Society- Somer Clinic
Protocol code: BIOXSOMCOV001
INVIMA protocol code: PI-CLS-1387
Protocol version and date: BIOXSOMCOV001 V.3 06_08_20
Specialty: Internal Medicine - Critical Medicine and Intensive Care
Study Phase: Phase II
Target population: Patients with SARS-CoV-2 infection, who develop respiratory distress syndrome with indication for ventilatory support in the intensive care unit.
Duration of the study: 11 months

Related documentation

1. Informed consent

Rionegro Medical Society- Somer Clinic
- Main informed consent BIOXSOMCOV001 V.3 11_08_20
- Legal representative informed consent BIOXSOMCOV001 V.2.11_08_20
- FR-INV-001 Informed Consent Umbilical Cord Donation V1 11_08_20

2. WJ-MSC Researcher Manual Version 1.0 13_July_2020

Paragraph 1: The sponsor is responsible for the veracity of the information provided and for compliance with the sanitary regulations under which the BIOXSOMCOV001 Study was approved and acquires the commitment to comply with the provisions of current sanitary regulations and / or work guidelines issued by the National Institute for Food and Drug Surveillance - INVIMA.

Paragraph 2: The sponsor acquires the commitment to have a current policy during the development of the clinical study.

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Paragraph 3: The sponsor agrees to provide the policy without the exclusion related to transmission of diseases and / or pandemics once they have it available. Until the policy rests in our file, the study cannot begin

SECOND ARTICLE: APPROVE for the reference protocol the following investigational drug:

Product Name and Concentration: Warthon's Jelly Mesenchymal Stem Cells.
Origin: Biological
Maker: BioXcellerator S.A.S
Pharmaceutical Form: Injectable solution
Route of administration: Intravenous
Packaging: Saline solution bag
Storage conditions: 4 ° C
Shelf life: 1 year

THIRD ARTICLE: APPROVE the arts presented by filing No. 20201092763 for the investigational drug described in the previous article.

ARTICLE FOUR: AUTHORIZE the following institution and Principal Investigator to develop the research protocol related in the first article.

RESEARCH CENTER	PRINCIPAL INVESTIGATOR
Rionegro Medical Society- Somer Clinic	Alfredo Hernández Ruiz

ARTICLE FIVE: NOTIFY this resolution by electronic means to the legal representative and / or attorney-in-fact of the owner, in accordance with the provisions of Article 4 of Decree 491 of March 28, 2020. Noting that only the appeal for reversal proceeds against it that must be filed with the Technical Director of Medicines and Biological Products of the National Institute for the Surveillance of Medicines and Food Invima within ten (10) days following notification, in the terms indicated in the Code of Administrative Procedure and of Administrative Litigation. The notification will be provided from the date and time that the administrator receives the administrative act.

ARTICLE SIX: This Resolution governs from the date of its execution

COMMUNICATE, BE NOTIFIED AND ENFORCE IT

It is issued in Bogotá D.C., on September 7, 2020
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Signature Not Verified
Digitally signed by DIANA MILENA CALDERON NOREÑA
Date: 09/07/2020 12:23:09 COT
Reason: Invima
Location: BOGOTA D.C., Colombia

DIANA MILENA CALDERON NOREÑA
TECHNICAL DIRECTOR FOR MEDICINES AND BIOLOGICAL PRODUCTS

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