

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Oct 2020

Effect of stromal vascular fraction (SVF), blood and condition medium derived exosomes on treatment of covid-19 patients with Acute Respiratory Distress Syndrome(ARDS)/ clinical Trial

Protocol summary

Study aim

The aim of this study was the efficacy of stromal vascular fractions, and also their conditioned media exosomes and blood exosomes in patients with covid-19 with acute respiratory distress syndrome /clinical trial in quality.

Design

This study is a multicenter, random, double-blind study in which patients with admission criteria will enter the study after obtaining conscious consent from themselves or legal guardians (this study will be conducted after the approval of the Ethics Committee of Tabriz University of Medical Sciences).

Settings and conduct

Subcutaneous fat is processed by the SVF separator(Lipogems), and will be purchased as a ready-made kit. Blood exosomes will also be isolated by ultracentrifuge. The conditioned medium obtained from SVF culture is collected to separate the exosome, after 6-8 hours three types of environment and autologous ready for injecton. These solutions are delivered in 3 consecutive days by delivering a volume of 10 ml through the trachea will be injected into the patient's lungs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Covid19 patients aged 15-70 years hospitalized in the ICU, which includes all confirmatory tests Satisfaction in studying Exlusion criteria: History of kidney transplantation History surgery on the lungs The presence of any malignancy Previous active infection Use immunosuppressive and other drugs The presence of autoimmune disease

Intervention groups

Patients will be divided in four control and experimental groups(60 patients: in each group of 15 patients). Routine control group with routine treatment Autologous SVF receiving group Autologous blood exosome group SVF Autologous Fluid Exposure Group It should be noted

that all groups receive the same common treatments.

Main outcome variables

SOFA score Lung damage score on days 0, 4, 7, 14a assess inflammatory status (IL1, IL6) Oxidative Status (TAC)

General information

Reason for update

Acronym

تاثیر قطعه عروقی استروما و آگزوزوم در بیماران کووید 19 مبتلا به سندرم دیسترس تنفسی حاد

IRCT registration information

IRCT registration number: **IRCT20200510047385N1**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Leila Roshangar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 3870

Email address

lroshangar@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of stromal vascular fraction (SVF), blood and condition medium derived exosomes on treatment of covid-19 patients with Acute Respiratory Distress Syndrome(ARDS)/ clinical Trial

Public title

Effects of SVF and exosome in covid-19 patients with acute respiratory distress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

covid19 patients hospitalized in the ICU, which includes all confirmatory tests - Satisfaction in studying

Exclusion criteria:

History of kidney transplantation History surgery on the lungs The presence of any malignancy Previous active infection Use immunosuppressive and other drugs The presence of autoimmune disease

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Participants are leading researchers, especially in trials initiated by academic researchers, health care personnel (physicians, nurses, etc.) who are responsible for patient care, data collection authorities and those Assessing the outcome will be blind. The Data Safety and Monitoring Committee will not be blind. To receive blood samples from patients, the relevant code of ethics will be obtained from the Ethics Committee of Tabriz University of Medical Sciences. In addition, patients will be given informed consent to participate in the study. This study has no cost for patients and patients can leave the study at any time. All patient information will be confidential.

Placebo

Not used

Assignment

Factorial

Other design features

Due to the fact that the approved kit for Svf separation will be used it is processed non-enzymatically and for a maximum of 2 hours and will be autologous and we will not have cell culture and will be done in the operating room, all the rules related to GCP, GMP will be considered

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

دانشگاه Ethics committee of tabriz University of Medical Sciences

Street address

no7, baghshomal ave, banafshe, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138664393

Approval date

2020-07-01, 1399/04/11

Ethics committee reference number

1399.095.IR.TBZMED.VCR.REC

Health conditions studied**1****Description of health condition studied**

Covid19

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Evaluation of inflammatory status IL1,

Timepoint

per 3 days

Method of measurement

Eliza

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients are divided into four control and experimental groups (60 patients: 15 patients in each group). Routine control group with routine treatment Receiver group SVF autologous group Blood exosome group Autologous group exposed to SVF autologous fluid It should be noted that all groups receive the same common treatments

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dr ata mahmoodpor

Street address

Attat ave, emam reza hospital

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imamreza@tbzmed.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

mohammad samiei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

40

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

leila Roshangar

Position

Academic member

Latest degree

Ph.D.

Other areas of specialty/work

Histology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be published in the form of an article

When the data will become available and for how long

2 year

To whom data/document is available

All

Under which criteria data/document could be used

Awareness and no conditions

From where data/document is obtainable

Article or email

What processes are involved for a request to access data/document

email

Comments